South Australia

Reproductive Technology (Code of Ethical Clinical Practice) Regulations 1995

under the *Reproductive Technology (Clinical Practices) Act 1988*

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Legislative history

1—Short title

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

3—Code of ethical (clinical) practice

For the purposes of the *Reproductive Technology (Clinical Practices) Act 1988*, the code of ethical practice set out in the Schedule is prescribed.

Schedule—Reproductive Technology Code of Ethical Clinical Practice

Part 1—Preliminary

1—Short title

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

2—Interpretation

In this code, unless the contrary intention appears—

Act means the *Reproductive Technology (Clinical Practices) Act 1988*;

artificial insemination by donor means an artificial fertilisation procedure (not being an in vitro fertilisation procedure or a surgical procedure) under which donor sperm are introduced, by artificial means, into the reproductive system of a woman;

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

counselling means a process of information sharing, decision-making or therapy that takes place during structured conversations between a counsellor and his or her client;

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 within the meaning of the *Prohibition of Human Cloning Act 2003*;

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;

embryologist means a person who—

(a) —

(i) is a medical practitioner; or

(ii) has qualifications in biological sciences; and

(b) is in charge of embryology in a reproductive medicine unit;

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;

gamete intra fallopian transfer means an artificial fertilisation procedure (not being an in vitro fertilisation procedure) by which sperm and ova are placed, by artificial means, directly into a fallopian tube of a woman;

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) a person who holds a licence under section 13(1) of the Act; or

(b) a registered medical practitioner to whom an exemption under section 13(7) of the Act applies;

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,

and ***husband***, ***wife*** and ***spouse*** have corresponding meanings;

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;

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

semen means human semen;

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.

2A—Compliance with NHMRC guidelines

Any clinical practice involving human reproductive material must be undertaken in compliance with the relevant requirements of the *Ethical Guidelines on the Use of Reproductive Technology in Clinical Practice and Research* published by the NHMRC.

Part 2—Prohibited practices

4—Prohibition on culturing or maintaining embryo outside body

A licensee must not 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 transfer of more than three embryos or ova in one cycle

A licensee must not place, or cause, suffer or permit to be placed, more than three embryos or three ova in the reproductive system of a woman in any one cycle of infertility treatment.

6—Prohibition on mixing of gametes or embryos from different sources

A licensee must not, in the same artificial fertilisation procedure, 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.

7—Prohibition on use of donor gametes in certain cases

(1) A licensee must not, in any infertility treatment, use, or cause, suffer or permit to be used, the reproductive material of a donor if the licensee knows or has reason to believe that the donor was, or may have been, at the time of donation, suffering from an illness, disease or genetic defect or trait for which screening is recommended by the Fertility Society donor screening guidelines.

(2) A licensee must not, in any infertility treatment, use, or cause, suffer, or permit to be used, the reproductive material of a donor if, in this State, 10 children have been born alive in consequence of infertility treatment using reproductive material of that donor unless—

(a) the material is to be used for the benefit of a married couple who have already had a child in consequence of the use of that donor's material; and

(b) the couple have requested in writing that the material of that donor be used for the purpose of conceiving another child.

8—Prohibition on use of gametes of close family members of recipients

A licensee, in giving infertility treatment to a married couple—

(a) must not, if the wife's ova are to be used in the treatment, use, or cause, suffer or permit to be used, sperm from the wife's father, son, brother or half-brother; and

(b) must not, if the husband's sperm are to be used in the treatment, use, or cause, suffer or permit to be used, the ova of the husband's mother, daughter, sister or half-sister.

9—Prohibition on use of embryos used in research

A licensee must not, in giving infertility treatment to a married couple, use, or cause, suffer or permit to be used, an embryo that has been used in research unless the licensee is of the opinion, after consultation with an embryologist, that there is a reasonable expectation of that embryo implanting and developing normally.

Part 3—Eligibility for infertility treatment and gamete donation

11—Eligibility for infertility treatment

(1) A licensee must not give infertility treatment, or cause, suffer or permit infertility treatment to be given, to a married couple unless the licensee has been furnished with—

(a) —

(i) a certified copy under seal of the couple's certificate of marriage; or

(ii) if the couple is not married but is cohabitating as husband and wife, a statutory declaration, signed by both spouses, setting out the period or periods of their cohabitation; and

(b) a letter of referral signed by a medical practitioner—

(i) —

(A) stating that the wife has been unable to conceive a child naturally and that the couple has undergone assessment or received preliminary treatment for infertility; or

(B) stating that, in his or her opinion, there is a risk that a genetic defect would be transmitted to any child conceived naturally by the wife and specifying the nature of that defect; and

(ii) stating that, in his or her opinion, neither spouse is, as at the date of the signing of the letter, suffering from any illness, disease or disability that would, in his or her opinion, interfere with the ability and capacity of the couple to care for a child throughout childhood; and

(c) a statutory declaration signed by both spouses, stating—

(i) that neither spouse is, as at the date of the signing of the declaration, subject to a term of imprisonment in this State or elsewhere or to outstanding charges (whether in this State or elsewhere) for an offence for which imprisonment may be imposed on conviction; and

(ii) that neither spouse has been found guilty, in this State or elsewhere, of a sexual offence involving a child; and

(iia) whether either spouse has been found guilty, in this State or elsewhere, of an offence involving violence; and

(iii) whether either spouse has had a child permanently removed from his or her guardianship under any Act or law of this State or any other place (other than by adoption).

(1a) If a statutory declaration under subclause (1)(c) reveals that either spouse—

(a) is subject to a term of imprisonment in this State or elsewhere or to outstanding charges (whether in this State or elsewhere) for an offence for which imprisonment may be imposed on conviction; or

(b) has been found guilty, in this State or elsewhere, of a sexual offence involving a child,

the licensee must not give infertility treatment to the person (or to the other spouse).

(1b) If a statutory declaration under subclause (1)(c) reveals that either spouse has been found guilty, in this State or elsewhere, of an offence involving violence (other than an offence within the ambit of subclause (1a)), the licensee must not give infertility treatment to the person (or to the other spouse) unless or until the review panel approves the provision of the treatment.

(1c) If a statutory declaration under subclause (1)(c) reveals that either spouse has had a child permanently removed from his or her guardianship under any Act or law of this State or any other place (other than by adoption), the licensee must refer the matter to the Child Protection Services unit of the Women's and Children's Hospital or the Flinders Medical Centre and must not give infertility treatment to the person (or to the other spouse) unless or until a clinician within the unit approves the provision of the treatment.

(2) A licensee must not give or continue to give infertility treatment, or cause, suffer or permit infertility treatment to be given or continued, to a married couple if—

(a) the licensee is satisfied that any of the information contained in a letter of referral or statutory declaration referred to in subclause (1) is false; or

(b) the licensee is satisfied that, since the signing of the statutory declaration referred to in subclause (1)(c)—

(i) either spouse has become ill, or is suffering from a disease or disability, and the licensee is of the opinion that the illness, disease or disability will interfere with the ability and capacity of the couple to care for a child throughout childhood; or

(ii) either spouse has commenced serving a term of imprisonment in this State or elsewhere; or

(iii) either spouse has been charged (whether in this State or elsewhere) with an offence for which imprisonment may be imposed on conviction and the charge has not been finally dealt with by a court or otherwise disposed of; or

(iv) either spouse has been found guilty, in this State or elsewhere, of a sexual offence involving a child; or

(v) either spouse has been found guilty, in this State or elsewhere, of an offence involving violence; or

(vi) either spouse has had a child permanently removed from his or her guardianship under any Act or law of this State or any other place (other than by adoption).

(3) In a case where subclause (2)(b)(v) applies (and the relevant offence does not fall within the ambit of subclause (2)(b)(ii), (iii) or (iv)), the licensee must not give or continue to give infertility treatment to the relevant couple without the approval of the review panel.

(3a) In a case where subclause (2)(b)(vi) applies, the licensee must not give or continue to give infertility treatment to the relevant couple without the approval of a clinician within the Child Protection Services unit of—

(a) the Women's and Children's Hospital facility of the Children, Youth and Women's Health Service Incorporated; or

(b) the Flinders Medical Centre facility of the Southern Adelaide Health Service Incorporated.

(3b) If a matter is referred under subclause (1c) or (3a), a clinician within the relevant unit must undertake an assessment of the couple's parenting skills and an approval must not be given under the relevant subclause unless the clinician is satisfied that there is a reasonable likelihood of the couple being able to care properly for, and nurture, a child throughout childhood.

(4) A licensee must not give infertility treatment, or cause, suffer or permit infertility treatment to be given, to a married couple unless the licensee is satisfied—

(a) that the couple has received adequate counselling from a medical practitioner or a counsellor regarding—

(i) the paramount importance of the welfare of any child that may be born in consequence of infertility treatment; and

(ii) the stress factors involved in the treatment; and

(b) that the couple has received adequate counselling from a medical practitioner regarding—

(i) the medical or surgical procedures involved in the treatment; and

(ii) the risks involved in the treatment; and

(iii) the likelihood of the various possible outcomes of the treatment; and

(c) that the husband and wife have been adequately informed by a medical practitioner or counsellor of—

(i) current knowledge and research about the psychological and physical outcomes of infertility treatment for children born in consequence of the application of artificial fertilisation procedures; and

(ii) where the couple is to receive infertility treatment involving the use of donor reproductive material—

(A) current opinion on the disclosure to children born in consequence of the use of donor reproductive material of the circumstances of their conception and the implications of secrecy on family relationships; and

(B) the right under this code of persons of or over the age of 16 who were born in consequence of the use of donor reproductive material to obtain access to non-identifying information about the donor or donors; and

(C) the availability of practical advice on what, when and how to disclose to children born in consequence of the use of donor reproductive material the circumstances of their conception; and

(d) where the couple is to receive infertility treatment involving the use of donor reproductive material and the licensee knows or has reason to believe that the identity of the donor is known to one or both spouses—

(i) that the couple have 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

(ii) that the donor has received adequate counselling from a medical practitioner or counsellor regarding the paramount importance of the welfare of any child that may be born in consequence of infertility treatment.

(5) If a licensee refuses to give infertility treatment to a married couple—

(a) on the ground that the licensee does not provide a form of treatment that meets the particular medical needs of the couple; or

(b) on the ground that the couple are unable to afford the cost of treatment,

the licensee must provide the couple with the name and address of such other licensee or licensees as he or she believes can—

(c) offer a form of treatment that may meet the medical needs of the couple; or

(d) provide treatment at a cost that the couple may be able to afford,

as the case may require.

(6) A licensee who refuses to give or to continue to give infertility treatment to a married couple must—

(a) on request by the couple, give the couple written reasons for the refusal; and

(b) where relevant, give the couple written information about the processes associated with the initiation of proceedings before the review panel.

12—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) and advising of the availability of counselling.

(2) A licensee must not accept the donation of reproductive material from any person if, after screening of the prospective donor in accordance with subclause (1)(a), the licensee has reason to believe that the prospective donor is or may be suffering from an illness, disease or genetic defect or trait for which the screening was carried out.

(3) A licensee must provide a prospective donor of reproductive material who signs a lifestyle declaration with a copy of the declaration.

13—Welfare of child to be paramount consideration of licensee

A licensee must, in deciding whether or not to give infertility treatment to any person, or to accept the donation of reproductive material from any person for use in infertility treatment, treat the welfare of any child that may be born in consequence of the treatment as the paramount consideration.

14—Licensee's discretion to refuse treatment

The provisions of this Part do not restrict a licensee's discretion to refuse to give or to continue to give infertility treatment to a person on any reasonable ground.

14A—The review panel

(1) The Minister must appoint a review panel for the purposes of this Part.

(2) The review panel will consist of five members, of whom—

(a) one (the presiding member) will be a legal practitioner; and

(b) one will be a member of the Council; and

(c) one will be a social worker, nurse or clinical psychologist who has experience in the field of child welfare; and

(d) one will be a person with expertise in the rehabilitation of persons who have committed offences involving violence; and

(e) one will be a person appointed to represent the interests of consumers of infertility treatment services.

(3) A member of the panel will be appointed for a term not exceeding three years on such conditions as the Minister may determine and will, at the expiration of a term of office, be eligible for reappointment.

(4) A person ceases to be a member of a panel if the person—

(a) resigns by notice in writing addressed to the Minister; or

(b) is removed from the panel by the Minister on the ground of misconduct, neglect of duty, incompetence or mental or physical incapacity to carry out official duties; or

(c) has completed a term of office and is not reappointed to the panel.

14B—Initiation of proceedings

(1) Proceedings before the review panel for the purposes of this Part must be initiated in a manner and form determined by the review panel.

(2) The purpose of any proceedings is to review the circumstances surrounding the offence or offences that have given rise to the proceedings before the review panel, and for the review panel to assess whether the welfare of any child born as a result of infertility treatment might be compromised on account of the commission of the offence or offences, and whether a licensee should be able to consider offering infertility treatment despite the offence or offences.

14C—Review by review panel

(1) For the purposes of this Part—

(a) proceedings before the review panel must be held without formality and in private; and

(b) the review panel is not bound by the rules of evidence, but may inform itself on any matter in such manner as the panel thinks fit.

(2) On proceedings before the review panel the licensee and the married couple may be assisted by an agent or representative (not being a legal practitioner).

(3) A decision of four members of the review panel is a decision of the panel.

(5) The review panel must give the licensee and married couple written reasons for the panel's decision under this Part.

14D—Appeal to Supreme Court

(1) A licensee or married couple aggrieved by a decision of the review panel under this Part may, in accordance with the rules of court, appeal to the Supreme Court against the decision.

(2) An appeal must be instituted within one month of the making of the decision being appealed against but the Court may, if it is satisfied that it is just and reasonable in the circumstances to do so, dispense with the requirement that the appeal be instituted within that period.

(3) On an appeal under this clause, the Court may—

(a) confirm the decision under appeal or set aside the decision;

(b) make any further or other order as to any other matter that the case requires.

14E—Welfare of child to be paramount consideration on review or appeal

The review panel or Supreme Court must, in making a determination under this Part, treat the welfare of any child that may be born in consequence of infertility treatment given to the married couple as the paramount consideration.

Part 4—Consent

Division 1—Consent to infertility treatment

15—Consent to treatment

(1) A licensee must not give infertility treatment or cause, suffer or permit infertility treatment to be given to any person unless the person and the spouse of that person have consented to the treatment in accordance with this Part.

(2) A consent to infertility treatment involving the use of an in vitro fertilisation procedure or gamete intra fallopian transfer procedure is effective—

(a) for three cycles of such treatment; or

(b) for 12 months,

whichever first occurs.

(3) A consent to infertility treatment involving an artificial insemination by donor procedure is effective—

(a) for six cycles of such treatment; or

(b) for 12 months,

whichever first occurs.

Division 2—Consent to collection of donor ova

16—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 3—Consent to storage and use of reproductive material

17—Consent to storage of gametes

A licensee must not keep semen or ova in storage or cause, suffer or permit semen or ova to be kept in storage unless—

(a) the person on whose behalf the semen or ova is to be stored; and

(b) if that person is not the person who produced the semen or ova—the donor of the sperm or ova,

has consented in accordance with this Part to the storage.

18—Consent to storage of embryos

(1) Subject to clause 26(2), a licensee must not keep an embryo in storage for the future use of a married couple, or cause, suffer or permit an embryo to be kept in storage for that purpose unless both the husband and the wife have consented in accordance with this Part to the storage.

(2) Consent to storage of an embryo may be given subject to conditions as to how the embryo is to be dealt with or disposed of.

19—Review of consent to storage of embryos

(1) A person on whose behalf an embryo is kept in storage by a licensee has (while the embryo remains in storage) the right to review the consent at intervals of 12 months.

(2) A licensee who keeps an embryo in storage on behalf of a married couple must, at least 90 days before each anniversary of the date on which consent to the storage was given, give the husband and the wife written notice informing them of their right to review their consent and inviting them to exercise that right.

20—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.

21—Consent to use in infertility treatment of embryos used in research

A licensee must not, in giving infertility treatment to a married couple, use, or cause, suffer or permit to be used, an embryo that has been used in research unless both the husband and the wife have consented in accordance with this Part to the use of that embryo in their infertility treatment.

Division 4—Consent to disclosure of confidential information

22—Consent to disclosure of confidential information

For the purposes of section 18(1)(c) of the Act and clause 36 of this code, the provisions of clause 23 apply in relation to the giving of consent by a person to the disclosure of information concerning himself or herself.

Division 5—General provisions

23—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—

(i) in the case of consent to infertility treatment, the married couple giving consent has, before signing the consent form, received—

(A) the counselling referred to in clause 11(4); and

(B) an information statement that complies with the *Reproductive Technology (Information Statements) Standard 1995* prepared by the Council, as in force from time to time; or

(ii) in the case of consent to the donation of reproductive material—

(A) the prospective donor 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

(B) where the licensee knows or has reason to believe that the identity of the prospective donor is known to one or both of the spouses for whose benefit reproductive material of the donor is to be used—the prospective donor has, before signing the consent form, received the counselling referred to in clause 11(4)(d); 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.

24—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.

25—Licensee to dispose of stored donor gametes in certain cases

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

26—Licensee to dispose of stored embryo in certain cases

(1) A licensee must dispose of an embryo that is kept in storage for the future use of a married couple if—

(a) the licensee becomes aware that the husband or wife has died or that their marriage has been dissolved; or

(b) the consent to the storage of the embryo is revoked in accordance with this Part by the husband or wife, or both.

(2) Subclause (1) does not apply where the conditions of a consent given under clause 18 specify how an embryo is to be dealt with or disposed of in the event that one or both of the spouses die, their marriage is dissolved or one or both of them become incapable of reviewing their consent, in which case the licensee must deal with the embryo or dispose of it in accordance with those conditions.

27—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 recipients of infertility treatment

28—Record to be kept

(1) A licensee must establish a record in relation to a married couple to whom the licensee is to give infertility treatment.

(2) The record must contain the following information:

(a) such information of a personal and medical nature concerning each of the spouses as good medical practice requires;

(b) full particulars of the couple's eligibility under the Act and this code for infertility treatment;

(c) in relation to counselling received by the couple pursuant to clause 11—

(i) the full name, business address and professional qualifications of the counsellor;

(ii) the dates on which the counselling was given;

(d) full particulars of any consent given by the couple under Part 4;

(e) a short summary (including the date on which it occurred) of any consultation with the couple in relation to the selection of the source of donor reproductive material to be used for the benefit of the couple;

(f) a short summary (including the date on which it occurred) of any consultation with an embryologist in relation to the use, in the couple's infertility treatment, of an embryo that has been used in research;

(g) in relation to infertility treatment given to the couple by the licensee—

(i) the numbers of cycles of treatment completed;

(ii) in relation to any drugs prescribed or administered during treatment—

(A) the name of the drug;

(B) the dosage prescribed or administered;

(C) the purpose for which the drug was prescribed or administered;

(iii) particulars of any medical or surgical procedures carried out;

(iv) the name of the person or persons who carried out those procedures;

(v) the results of any laboratory tests performed to monitor responses to treatment;

(vi) if infertility treatment is discontinued by the licensee, the reasons for the discontinuance;

(vii) in relation to any artificial fertilisation procedure resulting in the fertilisation of one or more ova—

(A) the nature of the procedure carried out;

(B) the time and date on which the procedure was carried out;

(C) the place at which the procedure was carried out;

(D) the name of the person or persons who carried out the procedure;

(E) whether sperm of the husband or a donor was used in the procedure;

(F) whether ova of the wife or a donor were used in the procedure;

(G) the number of ova fertilised;

(H) if one or more fertilised ova were placed in the body of the wife immediately after fertilisation, the number of fertilised ova so placed;

(I) if any fertilised ova were not placed in the body of the wife immediately after fertilisation, whether, and how many, fertilised ova were put into storage, disposed of or used for some purpose other than in the treatment of the couple;

(h) the outcome of each pregnancy established in consequence of infertility treatment given by the licensee;

(i) in relation to each child born in consequence of infertility treatment given to the couple by the licensee—

(i) such information of a personal and medical nature concerning the child as good obstetric practice requires;

(ii) full particulars of the child's state of health at the age of 28 days;

(j) such other information as the couple request to be included in the record.

(3) Where a licensee carries out an artificial fertilisation procedure in consequence of which a pregnancy is established using donor reproductive material donated to the licensee, the licensee must ensure that the record kept by the licensee under this code in relation to the married couple for whose benefit the pregnancy was established is cross-referenced to the record kept by the licensee under this code in relation to the donor.

(4) For the purposes of subclause (3), a licensee must cross-reference information by means of a code to which only the licensee and persons employed and authorised by the licensee have access.

29—Access to record

(1) A licensee must, on application in writing by a married couple in relation to whom a record is kept by the licensee under this Division, provide the couple with a copy of the record.

(2) A licensee must, on application in writing by a person to whom the licensee is giving or has given infertility treatment, provide the person with a copy of such portions of the record kept by the licensee under this Division as relate solely to the person.

(3) Where donor reproductive material has been used for the benefit of a married couple and a child has been born in consequence of that use, the licensee to whom the reproductive material was donated must, on application by the donor, provide the donor with a copy of all non-identifying information kept by the licensee under this Division in relation to the couple.

(4) A licensee to whom reproductive material is donated must, on application by the donor, inform him or her of the number and sex of children (if any) born in consequence of the use of his or her reproductive material.

Division 2—Records relating to donors of reproductive material

30—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.

31—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 3—Other records

32—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.

33—Records to be kept of clinical standards and procedures

A licensee must establish and maintain detailed records relating to all clinical and laboratory standards and procedures used by the licensee in the provision of infertility treatment services.

34—Record to be kept of criteria for use of certain embryos in infertility treatment

A licensee must keep a record of the criteria used by the licensee for determining whether embryos that have been used in research are suitable for use in infertility treatment.

Division 4—General provisions

35—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 Minister.

(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.

36—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.

37—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.

38—Period for which records must be preserved

(1) Subject to subclause (2), 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.

(2) Where no pregnancies have been established as a result of the use of a donor's reproductive material, a licensee who keeps a record relating to the donor under this Part must preserve the record for seven years from the date on which the last entry was made in the record.

39—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.

40—Amendment of personal records

A licensee must, on application by a recipient of infertility treatment or 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

41—Medical practitioner to be assigned to recipients of infertility treatment

A licensee must not give infertility treatment, or cause, suffer or permit infertility treatment to be given, to a married couple unless the licensee has first assigned a medical practitioner to be primarily responsible for the management of the couple's treatment.

42—Licensee to select donor gametes to be used in particular cases

A licensee must not, in giving infertility treatment to a married couple, use, or cause, suffer or permit to be used, any donor reproductive material unless the source of the material to be used for that couple has been selected in consultation with the couple by the licensee or a person authorised by the licensee.

43—Licensee to notify child or parents of any hereditary illness etc of donor

(1) Where—

(a) a child is born in consequence of the use of donor reproductive material by a licensee; and

(b) it comes to the knowledge of the licensee that, since the birth of the child, the donor, or some other child of whom the donor is a biological parent, has been diagnosed by a medical practitioner as suffering from a hereditary illness or disease,

the licensee must obtain the opinion of a medical practitioner with expertise in the field of genetics as to—

(c) the likely effects of the hereditary illness or disease on the health and life expectancy of a person suffering from the illness or disease; and

(d) the likelihood of the child referred to in paragraph (a) developing the hereditary illness or disease.

(2) The licensee must, as soon as practicable after receipt of the opinion, give a written notice that complies with this clause—

(a) if the child is of or over the age of 16 years—to the child;

(b) if the child is under the age of 16 years—to his or her parents.

(3) A notice under this clause must—

(a) specify that the donor or child of whom the donor is a biological parent has been diagnosed by a medical practitioner as suffering from a hereditary illness or disease and set out the nature of the illness or disease; and

(b) explain the likely effects of the illness or disease on the health and life expectancy of a person suffering from the illness or disease; and

(c) specify the likelihood of the child referred to in subclause (1)(a) developing the hereditary illness or disease; and

(d) specify the names and addresses of counsellors who may be available to provide counselling.

44—Licensee to notify gamete donor of hereditary illness etc of biological child of donor

(1) Where—

(a) a child is born in consequence of the use of donor reproductive material; and

(b) it comes to the knowledge of the licensee to whom the reproductive material was donated that the child has been diagnosed by a medical practitioner as suffering from a hereditary illness or disease,

that licensee must obtain the opinion of a medical practitioner with expertise in the field of genetics as to—

(c) the likely effects of the hereditary illness or disease on the health and life expectancy of a person suffering from the illness or disease; and

(d) the likelihood of the donor developing the hereditary illness or disease.

(2) The licensee must, as soon as practicable after receipt of the opinion, give the donor a written notice that—

(a) specifies that a child of whom the donor is a biological parent has been diagnosed by a medical practitioner as suffering from a hereditary illness or disease and set out the nature of the illness or disease; and

(b) explains the likely effects of the illness or disease on the health and life expectancy of a person suffering from the illness or disease; and

(c) specifies the likelihood of the donor developing the hereditary illness or disease; and

(d) specifies the names and addresses of counsellors who may be available to provide counselling.

45—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.

46—Annual report to Council

(1) A licensee must, not later than 28 February in each year, furnish to the Council a report relating to such matters as the Council may determine by written notice given to the licensee.

(2) In making a determination for the purposes of subclause (1), the Council must take into account any relevant requirements or guidelines imposed or published by the NHMRC with respect to the regulation of reproductive technology, and may take into account such other matters as the Council thinks fit.

47—Notification of accreditation status to Council

(1) A licensee must, at least once every three years, give the Council written notice of the status of the licensee's accreditation by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia to carry out artificial fertilisation procedures.

(2) A notice under subclause (1) must be accompanied by the relevant letters, certificates or other written evidence of the accreditation.

(3) A licensee must, as soon as practicable after any change in the licensee's accreditation status becomes known to the licensee, give the Council a written notice setting out full details of the change.

48—Notification of birth defects

A licensee must, as soon as practicable after becoming aware that a child born in consequence of infertility treatment given by the licensee is suffering from any birth defect, give the Pregnancy Outcome Unit of the Department of Human Services written notice of the birth defect, specifying the nature of the defect.

49—Service

A notice or document required or authorised by this code to be given to a person may be given personally or posted to the person's last known address.

Legislative history

Notes

- Variations of this version that are uncommenced are not incorporated into the text.
- Please note—References in the legislation to other legislation or instruments or to titles of bodies or offices are not automatically updated as part of the program for the revision and publication of legislation and therefore may be obsolete.
- Earlier versions of these regulations (historical versions) are listed at the end of the legislative history.
- For further information relating to the Act and subordinate legislation made under the Act see the Index of South Australian Statutes.

Principal regulations and variations

New entries appear in bold.

Year	No	Reference	Commencement
1995	189	*Gazette 5.10.1995 p922*	11.7.1996: r 2
1999	110	*Gazette 3.6.1999 p3005*	22.10.1999: r 2
2000	169	*Gazette 6.7.2000 p42*	6.7.2000: r 2
2003	251	*Gazette 18.12.2003 p4567*	2.4.2004: r 2
2004	**147**	***Gazette 8.7.2004 p2475***	**26.10.2004: r 2**
2005	170	*Gazette 21.7.2005 p2481*	uncommenced

Provisions varied

New entries appear in bold.

Entries that relate to provisions that have been deleted appear in italics.

Provision	How varied	Commencement
r 2	*omitted under the Legislation Revision and Publication Act 2002*	*2.4.2004*
r 3	substituted by 251/2003 r 4	2.4.2004
Sch		
cl 2		
the Act	*deleted by 251/2003 r 5(1)*	*2.4.2004*
Act	inserted by 251/2003 r 5(1)	2.4.2004
embryo	substituted by 251/2003 r 5(2)	2.4.2004
NHMRC	inserted by 251/2003 r 5(3)	2.4.2004
cl 2A	inserted by 251/2003 r 5(4)	2.4.2004
cl 3	*deleted by 251/2003 r 5(5)*	*2.4.2004*
cl 4	(a) deleted by 251/2003 r 5(6)	2.4.2004
cl 10	*deleted by 251/2003 r 5(7)*	*2.4.2004*
cl 11		
cl 11(1)	varied by 110/1999 r 3(a)	22.10.1999

cl 11(1a)—(1c)	inserted by 251/2003 r 5(8)	2.4.2004
cl 11(2)	varied by 110/1999 r 3(b)	22.10.1999
	varied by 251/2003 r 5(9)	2.4.2004
cl 11(3)	substituted by 251/2003 r 5(10)	2.4.2004
cl 11(3a)	inserted by 251/2003 r 5(10)	2.4.2004
	varied by 147/2004 r 4	**26.10.2004**
cl 11(3b)	inserted by 251/2003 r 5(10)	2.4.2004
cl 11(6)	substituted by 110/1999 r 3(c)	22.10.1999
	substituted by 251/2003 r 5(11)	2.4.2004
cl 14A	inserted by 110/1999 r 3(d)	22.10.1999
cl 14B	inserted by 110/1999 r 3(d)	22.10.1999
	substituted by 251/2003 r 5(12)	2.4.2004
cl 14C	inserted by 110/1999 r 3(d)	22.10.1999
cl 14C(1)	varied by 251/2003 r 5(13)	2.4.2004
cl 14C(4)	deleted by 251/2003 r 5(14)	2.4.2004
cl 14C(5)	varied by 251/2003 r 5(15)	2.4.2004
cl 14D	inserted by 110/1999 r 3(d)	22.10.1999
r 14D(1)	varied by 251/2003 r 5(16)	2.4.2004
cl 14E	inserted by 110/1999 r 3(d)	22.10.1999
	varied by 251/2003 r 5(17)	2.4.2004
cl 35		
cl 35(2)	varied by 169/2000 r 3	6.7.2000
cl 46	substituted by 251/2003 r 5(18)	2.4.2004
cl 48	varied by 169/2000 r 4	6.7.2000

Historical versions

2.4.2004