

SOUTH AUSTRALIA

**REPRODUCTIVE TECHNOLOGY (CODE OF ETHICAL CLINICAL
PRACTICE) REGULATIONS 1995**

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REGULATIONS UNDER THE REPRODUCTIVE TECHNOLOGY ACT 1988

*Reproductive Technology (Code of Ethical Clinical Practice)
Regulations 1995*

being

No. 189 of 1995: *Gaz.* 5 October 1995, p. 922¹

¹ Came into operation 11 July 1996: reg. 2.

N.B. The amendments effected to these regulations by Regulation No. 110 of 1999 have not been brought into operation.

2.

Citation

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

Commencement

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

Code of ethical (clinical) practice

3. For the purposes of the *Reproductive Technology Act 1988* (other than for the purposes of section 14(2)(c) of that Act), the code of ethical practice set out in the schedule is prescribed.

SCHEDULE

Reproductive Technology Code of Ethical Clinical Practice

**PART 1
PRELIMINARY**

Citation

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

Interpretation

2. In this code, unless the contrary intention appears—

"**the Act**" means the *Reproductive Technology Act 1988*;

"**artificial insemination by donor**" means an artificial fertilization procedure (not being an in vitro fertilization 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 II 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;

"**embryo flushing**" means a surgical procedure by which an ovum in the process of fertilization, 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 fertilization procedure (not being an in vitro fertilization 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 fertilization 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;

"**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

5.

- (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.

6.

**PART 2
PROHIBITED PRACTICES**

Prohibition on embryo flushing

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

Prohibition on culturing or maintaining embryo outside body

4. 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 fertilization; 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 fertilization.

Prohibition on transfer of more than three embryos or ova in one cycle

5. 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.

Prohibition on mixing of gametes or embryos from different sources

6. A licensee must not, in the same artificial fertilization 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 fertilization of ova produced by the one woman by sperm produced by the one man.

Prohibition on use of donor gametes in certain cases

7. (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.

Prohibition on use of gametes of close family members of recipients

8. 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.

Prohibition on use of embryos used in research

9. 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.

Prohibition on giving value for gamete donation

10. (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 INFERTILITY TREATMENT AND GAMETE DONATION

Eligibility for infertility treatment

11. (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, whether in this State or elsewhere—
 - (A) of a sexual offence involving a child; or
 - (B) 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).

9.

(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, whether in this State or elsewhere—
 - (A) of a sexual offence involving a child; or
 - (B) of an offence involving violence.

(3) A licensee may refuse to give or to continue to give infertility treatment to a married couple if—

- (a) either spouse has had, or has, 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); and
- (b) the licensee is of the opinion, after assessment of the couple's parenting skills by a medical practitioner or counsellor at the Child Protection Services unit of the Women's and Children's Hospital or the Flinders Medical Centre, that there is a reasonable likelihood of the couple not properly caring for or nurturing 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 fertilization 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 infertility treatment to a married couple must, on request by the couple, give the couple written reasons for the refusal.

Eligibility for donation of reproductive material

12. (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.

Welfare of child to be paramount consideration of licensee

13. 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.

12.

Licensee's discretion to refuse treatment

14. 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.

**PART 4
CONSENT**

DIVISION 1—CONSENT TO INFERTILITY TREATMENT

Consent to treatment

15. (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 fertilization 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

Consent to collection of donor ova

16. 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

Consent to storage of gametes

17. 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.

Consent to storage of embryos

18. (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.

Review of consent to storage of embryos

19. (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.

Consent to use of gametes and embryos

20. 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.

Consent to use in infertility treatment of embryos used in research

21. 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

Consent to disclosure of confidential information

22. 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

Form of consent, etc.

23. (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

15.

- (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.

Licensee to provide copy of consent form

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

Licensee to dispose of stored donor gametes in certain cases

25. 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.

Licensee to dispose of stored embryo in certain cases

26. (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.

Effect of this Part on other laws

27. 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**

Record to be kept

28. (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 fertilization procedure resulting in the fertilization 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 fertilized;
 - (H) if one or more fertilized ova were placed in the body of the wife immediately after fertilization, the number of fertilized ova so placed;
 - (I) if any fertilized ova were not placed in the body of the wife immediately after fertilization, whether, and how many, fertilized 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 fertilization 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.

Access to record

29. (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

Record to be kept

30. (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;

20.

- (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.

Access to record

31. (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

Records to be kept relating to reproductive material

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

Records to be kept of clinical standards and procedures

33. 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.

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

34. 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

Confidentiality

35. (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 Commission.

(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.

Access to personal information

36. (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.

Documents to be preserved

37. 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.

Period for which records must be preserved

38. (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.

Maintenance of records

39. 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.

Amendment of personal records

40. 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**

Medical practitioner to be assigned to recipients of infertility treatment

41. 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.

Licensee to select donor gametes to be used in particular cases

42. 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.

Licensee to notify child or parents of any hereditary illness, etc. of donor

43. (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.

Licensee to notify gamete donor of hereditary illness, etc. of biological child of donor

44. (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.

Availability of Act and regulations for inspection

45. 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.

Annual report to Council

46. 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 infertility treatment given by the licensee in the previous calendar year—
 - (i) the number of couples to whom treatment was given;
 - (ii) the types of infertility for which treatment was given;

- (iii) if the licensee gave infertility treatment to any married couples to avoid a risk of transmitting a genetic defect by natural conception—the nature of genetic defects;
 - (iv) the nature of the treatment given;
- (b) in relation to each kind of artificial fertilization procedure carried out by the licensee in the previous calendar year—
- (i) the number of cycles of treatment begun;
 - (ii) the number of cycles of treatment involving the use of the husband's sperm;
 - (iii) the number of cycles of treatment involving the use of donor sperm;
 - (iv) the number of cycles of treatment involving the use of the wife's ova;
 - (v) the number of cycles of treatment involving the use of donor ova;
 - (vi) the number of cycles of treatment involving the use of a donated embryo;
 - (vii) the number of cycles of treatment involving the use of an embryo produced using the wife's and husband's reproductive material and frozen and thawed prior to use;
- (c) in relation to pregnancies established in consequence of infertility treatment given by the licensee in the previous calendar year and in relation to each kind of artificial fertilization procedure carried out by the licensee—
- (i) the number of pregnancies established;
 - (ii) the number of single, twin, triplet and quadruplet pregnancies;
 - (iii) the number of resulting live births and still-births;
 - (iv) the number of terminations of pregnancies;
 - (v) the number of miscarriages of pregnancies;
 - (vi) the number of ectopic pregnancies resulting in the loss of the foetus;
- (d) in relation to pregnancies established in consequence of infertility treatment given by the licensee in the previous calendar year using an embryo that has been used in research—
- (i) the number of pregnancies established;
 - (ii) the number of single, twin, triplet and quadruplet pregnancies;
 - (iii) the number of resulting live births and still-births;

- (iv) the number of terminations of pregnancies;
 - (v) the number of miscarriages of pregnancies;
 - (vi) the number of ectopic pregnancies resulting in the loss of the foetus;
- (e) in relation to children born in the previous calendar year in consequence of infertility treatment given by the licensee—
- (i) the total number of children who have survived 28 days;
 - (ii) the number of children who have survived 28 days who were born in consequence of the use of an embryo that has been used in research;
- (f) the number of married couples awaiting infertility treatment at the end of the previous calendar year;
- (g) 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 infertility treatment for the benefit of other married couples;
 - (vii) the number of embryos donated for use in research;
- (h) 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 infertility treatment;
 - (iv) in the case of a licensee who holds a licence under section 14(1) of the Act—the number of embryos used by the licensee in research;
 - (v) the number of embryos transferred to another licensee;
 - (vi) the number of embryos transferred out of the State;
 - (vii) the number of embryos disposed of by the licensee;

- (viii) the number of embryos in storage at the end of the year;
- (i) in relation to women to whom the licensee gave infertility treatment in the previous calendar year—
 - (i) the number of women who required hospitalisation for a serious medical condition associated with that treatment and the nature of those medical conditions;
 - (ii) the number of deaths from causes associated with that treatment;
- (j) such other information as the Council may require by notice in writing given to the licensee.

Notification of accreditation status to Council

47. (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 fertilization 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.

Notification of birth defects to Commission

48. 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 Commission written notice of the birth defect, specifying the nature of the defect.

Service

49. 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.