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HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

DIRECTIONS

Given by the Commissioner of Health to set the standards of practice under the Human Reproductive Technology Act 1991 on the advice of the WA Reproductive Technology Council

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INTRODUCTION TO THE DIRECTIONS

The Human Reproductive Technology Act 1991 came into operation on 8 April 1993. The Act is intended to regulate and monitor the development and use of assisted fertilisation procedures and reproductive technology, while maintaining sensitivity to the welfare of the infertile. Research or treatment which involves the creation of human embryos, their storage, and the storage of donated human eggs and sperm are all regulated under the Act, which establishes a system of licensing for those practitioners undertaking the various procedures of reproductive technology. The Act covers IVF, GIFT and artificial insemination, and imposes obligations upon those offering these treatments.

The Act also establishes the Western Australian Reproductive Technology Council, for which one important task is to advise the Commissioner of Health on all matters relating to licensing, including the setting of suitable standards for licensees. These Directions from the Commissioner of Health not only set these standards, they also serve as a useful consultation document upon which interested members of the community may comment. In the initial stages of administration of the requirements of the Act the Council has faced many fundamental ethical and social questions, and many complexities in addressing the efficacy and safety of clinical or scientific practices and their suitable regulation.

It is recognised that infertile people undergoing treatment deserve and should expect proper consideration of their medical and social needs. However the welfare of future generations, especially the interests of any children who may be born as a result of the procedures, must also be addressed. For example the Council, through the Public Health IVF Register, will be able to monitor the procedures, especially for their long-term outcomes and safety with respect to any children born and to participants. The Donor Register will record information about donors of human reproductive material and children born as a result of this donation. Access to non-identifying information from this Register by donors, recipients, offspring or researchers has been provided for under the Act, as this information may be of medical or social significance in the future.

These Directions are issued on the advice of the Council and must be complied with by the licensees until revoked or until the Code of Practice, once completed and receiving Parliamentary approval pursuant to S. 16 of the Act, prevails. Guidelines for licensees have also been developed by the Council, and these are intended to assist in compliance with the Directions.

In the framing of the Directions the Council has taken into account the following requirements of the Human Reproductive Technology Act—

- the respect which should be given to human life at all stages of its development;
- the help and encouragement that should be given to couples who are unable to conceive children naturally or whose children may be affected by a genetic disease;
- the welfare of any children who may be born as a result of treatment; and
- the recognition that the responsible pursuit of medicine and science may lead to benefits for individuals and for society.

It is recognised that in some cases there may be conflict between some of these important considerations. In attempting to resolve this conflict and in accordance with the spirit and intentions of the Act, it is the aim of the Council to support the best clinical and scientific practice, while protecting the rights of people requiring access to reproductive technology.

All constructive comments on the Directions are welcome and may be addressed to—

The Executive Officer,
Western Australian Reproductive Technology Council
189 Royal Street
EAST PERTH 6004.
Phone: (08) 9222 4260
Fax: (08) 9222 4236

PRELIMINARY

Unless otherwise provided, all words and phrases in these directions have the same meaning as the Human Reproductive Technology Act 1991.

"the Act" includes the Human Reproductive Technology Act 1991, the Human Reproductive Technology Amendment Act 1996, the regulations and directions published in the Gazette.

"embryo" includes a reference to an egg in the process of fertilisation.

"required" means required by the Act.

"Schedule" means schedule to these directions;

"guidelines" means guidelines to these directions;

Under section 33 of the Human Reproductive Technology Act, a contravention of a direction may constitute grounds for disciplinary action, and may be taken into account when considering any application. Disciplinary action is provided by Division 3 Part 4 of the Act.

* An asterisk indicates directions of relevance to holders of an Exemption.

Copies of the Act may be obtained from—

State Law Publisher
Ground Floor
10 William Street
Perth WA 6000
Tel (08)9321 7688
Fax (08)9321 7536

SECTION 1: PERSONNEL, PREMISES AND MINIMUM STANDARDS OF PRACTICE

Part 4 of the Act.

STANDARDS OF PRACTICE, PERSONNEL AND PREMISES REQUIRED FOR A PRACTICE LICENCE.

1.1 The Licensee and person responsible in relation to a Practice Licence that authorises IVF procedures must ensure that:

the minimum standards maintained for practice, personnel and premises are those set by the Reproductive Technology Accreditation Committee (RTAC) and the National Association of Testing Authorities (NATA);

counselling by an "approved counsellor" who is eligible for full membership of the Australian and New Zealand Infertility Counsellors' Association (ANZICA) is provided, in accordance with section 5 of the Directions; and

that any other standards established under the Act are complied with.

1.2 The Licensee and person responsible in relation to a Practice Licence that only authorises artificial insemination and related research must ensure that standards for practice, equipment, staff and facilities comply with the standards of good medical practice and the Act.

STANDARDS OF PRACTICE, PERSONNEL AND PREMISES FOR A STORAGE LICENCE.

1.3 The Licensee and person responsible in relation to a Storage Licence authorising collection and storage of sperm for artificial fertilisation procedures involving donation, and/or the storage of eggs or embryos, must comply with, as a minimum, any standards set by RTAC/NATA for practice, personnel and premises, and ensure that the staff includes a medical practitioner.

1.4 The Licensee and person responsible in relation to a Storage Licence which authorises the storage of donor sperm which is not collected, or sperm collected for artificial fertilisation procedures not involving donation, must ensure that the minimum standards for practice, equipment, staff and facilities comply with those required of good medical practice and the Act.

STANDARDS FOR AN EXEMPTION FOR ARTIFICIAL INSEMINATION.

*1.5 To be eligible for an exemption from the licensing requirement for carrying out artificial insemination, a person must be a currently registered medical practitioner. Evidence of registration, and a written undertaking by the medical practitioner to comply with the Code and Directions, must be given at the time of application for exemption, in accordance with the prescribed application form.

APPLICATION FOR RENEWAL OF A LICENCE.

1.6 A Licensee must apply for renewal of a licence no later than three months before its expiry.

SECTION 2: RECORDS AND REPORTING

Part 4, Division 5 of the Act.

RECORD KEEPING:

Records to be kept by Practice licensees

2.1 A Practice licensee must maintain complete records of all artificial fertilisation procedures carried out, in accordance with the Act and in accordance with the standards of good medical practice, with sufficient detail to enable compliance with reporting requirements under the Act.

Records about storage or use of semen for AIH or DI

2.2 A Storage licensee must record, for all those for whom semen stored is for their own use or for donation (Artificial insemination by husband (AIH) or Donor insemination (DI)), information including the number of semen samples collected and/or stored, details of use, transfer to another Storage licensee, discarding, approved experimentation with dates, and outcome of any use (or reasons why an outcome is unknown).

*2.3 All Licensees or Exempt practitioners collecting and using semen for AIH not involving storage must keep records of the use and outcome of any such procedures performed, in accordance with the standards of good medical practice .

Records on the use of donor semen by an Exempt practitioner

*2.4 Licensees and Exempt practitioners must keep records of all uses of donor semen in an artificial fertilisation (AF) procedure, including details of any semen samples collected or used, the identity of any recipient, and outcome of each procedure (or the reason why the outcome is unknown).

Records about embryo storage

2.5 Storage licensees must record information on all embryos stored, including the relevant consents that identify current rights to deal with and dispose of each embryo stored, details of all disposals, transfers to other Storage licensees, Council approved experimentation or diagnostic testing involving these embryos, and dates and outcomes of any use (or reasons why such dates and outcomes are unknown).

Period records to be retained

*2.6 Licensees and Exempt practitioners must retain required records for 25 years.

Communication of information with a referring doctor

*2.7 A Licensee or Exempt practitioner may provide a referring doctor with information which has been obtained under the Act including the identity of any participant, donor, or child born as a result of any artificial fertilisation procedure, in accordance with the standards of good medical practice.

TRANSFER OF RESPONSIBILITY TO REPORT TO THE REGISTERS

2.8 Where a Storage licensee transfers stored gametes or any stored embryo to another Storage licensee, the original Storage licensee must provide all required information to the IVF Register and/or the Donor Register, unless he/she can show written evidence that the other licensee has agreed to provide this information.

2.9 Where a Storage licensee agrees in writing to provide all required information to the IVF Register and/or the Donor Register, that licensee must provide the required information to the Registers.

REPORTING TO THE IVF REGISTER

Content

2.10 A Practice licensee must provide the IVF Register with information about IVF participants and treatments in accordance with Forms 1-3 of the Schedule to these Directions.

Timing and manner of transfer of information to the IVF Register

2.11 A Practice licensee must provide the required information to the IVF Register including:

(i) In relation to named identifying information about participants and their husbands, wives or de facto partners where non-identifying information is already registered, when or as requested by the Register staff;

(ii) In relation to non-identifying information about participants and treatment details for all treatment cycles:

for treatment commenced between January 1 and April 30, before October 31 in the same year;

for treatment commenced between May 1 and August 31, before February 28 the following year; and

for treatment commenced between September 1 and December 31, before June 30 the following year.

2.12 A Practice licensee must provide the required information to the IVF Register in the following manner:

(i) in relation to named identifying information, in accordance with Form 1 of the Schedule and, where practicable, provided on computer disc in an ASCII file or other compatible format;

(ii) all other information, in accordance with Forms 2-3 of the Schedule.

REPORTING TO THE DONOR REGISTER ABOUT THE USE OF DONATED REPRODUCTIVE MATERIAL

Content

*2.13 A Licensee or holder of an Exemption who is required to provide information about the use of donated human reproductive material in an artificial fertilisation procedure to the Donor Register, must provide the information in accordance with Forms 4-7 of the Schedule, in the required manner.

*2.14 A Licensee or holder of an Exemption is not required to supply information to the Donor Register that includes the identity of the donor of any human reproductive material used—

(i) in respect of embryos already in store at the time the Act came into operation, where the donor did not agree to the disclosure of his or her name to the Register at the time the gametes were provided, and

(a) the person responsible has not been able to contact the donor to obtain his or her agreement to the registration of his or her name despite reasonable efforts to do so; or

(b) the donor has been asked to agree to the registration of his or her identity and has refused; and

(ii) in respect of donor gametes in store at the time the Act came into operation, where the donor did not agree to the disclosure of his or her name to the Register at the time the gametes were provided and, prior to the Act coming into operation, a woman entered into an agreement with a licensee that the gametes would be stored for treatment to provide her with a full sibling for an existing donor child, and

(a) the person responsible has not been able to contact the donor to obtain his or her agreement to the registration of his or her name despite reasonable efforts to do so; or

(b) the donor has been asked to agree to the registration of his or her identity and has refused.

A Licensee or holder of an Exemption must, at the time of registration of information, provide the reasons for non-inclusion of identity of the donor.

Use of donor sperm

• Reporting back to the Storage licensee and Register about the use of donor semen

*2.15 All Exempt practitioners, and Licensees using or dispensing donor semen that has been collected and supplied to them by another Storage licensee, must provide that Storage licensee with information about the use and subsequent outcome of any semen provided. In cases of ongoing clinical pregnancy the identity and date of birth of the recipient must be reported directly to the Donor Register, on request by the Register staff.

• Reporting by the Storage licensee to the Donor Register about donor sperm collected by the Storage licensee

2.16 Subject to Directions 2.8 and 2.9, all Storage licensees who collect and dispense donor semen are responsible for reporting to the Register all required information about the use of such semen and subsequent outcomes, unless an Exempt practitioner, Practice licensee or other person under their supervision has failed to provide the Storage licensee with the required information. The Storage licensee must, at the time of providing information, advise the Register staff why the required information is not provided.

• Reporting directly to the Register when donor semen is not supplied by a Storage licensee

*2.17 Exempt practitioners or Practice licensees using donor semen not supplied by a Storage licensee must provide all required information to the Register.

Stored eggs or embryos

• Eggs or Embryos supplied by a Storage licensee

2.18 A Practice licensee using eggs or embryos, including donor egg embryos or donor embryos, which have been supplied to them by a Storage licensee, must provide the Storage licensee with information about their use in an artificial fertilisation (AF) procedure and subsequent outcome of this use, including the treatment cycle code.

2.19 Subject to Directions 2.8 and 2.9, a Storage licensee who stores donor eggs, donor egg embryos or donor embryos must provide the Register with all the required information about their use, and outcomes of any AF procedures.

• Fresh donor eggs or embryos

2.20 Where storage is not involved, a Practice licensee using donor eggs, donor egg embryos or donor embryos in an AF procedure must provide the Register with the required information.

Maximisation of information transfer

*2.21 A Storage licensee may only provide semen to a medical practitioner for DI if that practitioner is currently exempt under the Act.

*2.22 A Storage licensee may not provide human reproductive material to any Practice licensee, Storage licensee, Exempt practitioner or any other person under their supervision, where that person has failed to provide the Storage licensee, within a reasonable time and without good reason, with information about the use of human reproductive material previously provided to them by that Storage licensee.

Timing of provision of information about donation to the Register

*2.23 Licensees and Exempt practitioners required to provide information to the Register must provide that information as follows:

(i) Identifying information

In relation to identifying information in accordance with Forms 6 and 7 of the Schedule, for any donor, or for any recipient of donated human reproductive material who appears to have achieved an ongoing clinical pregnancy (at 8 weeks for DI and 20 weeks for IVF) or for whom the outcome is unknown, when or as requested by Register staff;

(ii) Donor personal information

In relation to non-identifying donor information in accordance with Form 4 of the Schedule for any donor of human reproductive material involved in an artificial fertilisation procedure where it appears an ongoing clinical pregnancy (at 8 weeks for DI and 20 weeks for IVF) has been achieved, or where the outcome of the procedure is unknown, when or as requested by Register staff;

(iii) DI treatment information

Licensees and Exempt practitioners must provide information in relation to DI treatments in accordance with form 5 of the Schedule at the following times:

for DI procedures carried out between January 1 and April 30, no later than October 31 the same year;

for DI procedures carried out between May 1 and August 31, no later than February 28 the following year;

for DI procedures carried out between September 1 and December 31, no later than June 30 the following year.

*2.24 Licensees and Exempt practitioners must provide the required information to the Donor Register in the following manner:

(i) in the case of identifying information being sent in bulk by the holder of a Storage or a Practice Licence, in accordance with Forms 6 and 7 of the Schedule and, where practicable, on computer disc in an ASCII file or other compatible format;

(ii) in the case of identifying information about donors or recipients being sent by the holder of an Exemption, in accordance with Form 7 of the Schedule;

(iii) other required information in accordance with Forms 4 and 5 of the Schedule.

ANNUAL REPORTING

Timing of Annual Reporting.

2.25 All Licensees who store eggs or embryos, and who collect and store donor semen, must submit an Annual Report to the Commissioner of Health by 31 July each year relating to the previous financial year from July 1 to June 30, as required by these directions.

Content of Annual Reporting by Storage licensees -

- about semen stored for donation

2.26 Storage licensees who collect and store semen must include the following information in their Annual Report:

- in relation to all semen stored for donation during the year

(i) # donors (total), with breakdown by

age;

marital status;

times supplying semen samples for storage during the year (not # straws obtained);

(ii) # new donors this financial year;

(iii) total # IVF/GIFT treatments for which donor semen was supplied to another licensee (give licence number) by the Storage licensee.

Note: No more data is required to be reported here by these licensees about donor sperm IVF.

(iv) the following additional information about semen provided for DI

licensees, # Exempt practitioners, # other non-medical agents supplied with semen for DI, (with Licence or Exemption numbers and any other relevant information to enable identification of licence or person supplied);

the frequency each was supplied; and

DI procedures carried out by the licensee.

- embryo storage

2.27 Storage licensees who store embryos must include the following information in their Annual Report:

(i) Total number of embryos put into storage in the previous financial year, from July 1 to June 30, with a breakdown showing:

frozen following IVF carried out by the licensee;

transferred from another WA Licensee (with Licensee codes); and

transferred from outside the State, with their source and reason why;

(ii) Total number of embryos removed from storage in the licensed practice in the same period, with a breakdown showing:

thawed for FET;

thawed with the intention of allowing them to succumb;

transferred to other WA Storage Licensees (with Licensee codes);

Transferred out of the state with information as to where these were sent, and why;

(iii) Total number of embryos in storage at the end of the financial year, June 30 .

Content of Annual Reporting by Practice Licensees

2.28 Practice licensees must include the following information in their Annual Report:

regarding IVF treatments—

(i) fresh ET:

Women treated

Treatment cycles begun

Cycles with oocyte retrieval

Cycles with embryo transfer

Cycles USING donor—

sperm

oocytes

embryos

Cycles where embryos were frozen

Cycles where donation occurred

cycles from which oocytes were donated

cycles from which embryos were donated.

Breakdown of the above treatment cycles with regard to the following techniques—

Cycles with:

IVF-ET and GIFT transfer in the same cycle;

micromanipulation, with a breakdown by type (eg ICSI);

sperm retrieval, with a breakdown by location (eg epididymis);

Fallopian embryo transfer;

(ii) regarding FET

Women treated

Treatment cycles begun

Cycles with embryo transfer

Cycles USING donor—

sperm

oocytes

embryos

Breakdown of the above treatment cycles with regard to type of transfer technique, such as—

cycles with Fallopian embryo transfer.

(iii) regarding GIFT—

Women treated

Treatment cycles begun

Cycles with oocyte retrieval

Cycles with gamete transfer

Cycles using donor—

sperm

oocytes

Cycles with IVF, (including those with ET in GIFT cycle reported in (ii) above)

Cycles with embryos frozen

Cycles from which oocytes were donated.

2.29 All Practice licensees must include the following information about artificial fertilisation procedures in the Annual Report:

(i) Statistical information on any serious morbidity associated with an artificial fertilisation procedure carried out under the licence, and the nature and severity of this;

(ii) statistical information on any mortality associated with an artificial fertilisation procedure carried out under the licensed practice, and the likely cause of this;

(iii) the number of intra-uterine insemination procedures carried out under the licence during the year, with a breakdown as shown in the tables below—

(a) Source of semen and use of ovulation induction.

Source of Semen	Ovulation Induction	# IUI procedures
donor	-nil	
	-clomiphene only	
	-with gonadotrophins	
husband/partner	-nil	
	-clomiphene only	
	-with gonadotrophins	
	Total # IUI procedures	

(b) Showing number of sacs on initial ultrasound (US) and (plurality of ongoing pregnancy (OP)) by ovulation induction method.

# Sacs or plurality of OP	Ovulation Induction			Total
	nil (# OP) # initial US	clomiphene only # initial US (# OP)	with gonadotrophins # initial US (# OP)	# initial US (#OP)
1				
2				
3				
4				
>4				
Total pregnancies initial US and (OP)				

Note: Examples to assist with the completion of this table may be found in the Guidelines to this section of the Directions.

(iv) information about artificial fertilisation procedures carried out on patients referred from the public infertility clinic at King Edward Memorial Hospital giving—

their ID numbers in the treating clinic;

for each person the number, dates of commencement and type of all artificial fertilisation procedures begun during the year (eg IVF, GIFT, AI, FET, and any use of donor, micromanipulation, IUI, tubal transfer etc).

(v) brief qualitative comments on any significant changes in the licensed practices during the year, including changes in medication regimes, collection techniques, use of natural cycles, and types of infertility being treated.

2.30 Licensees must include the following additional information in the Annual Report:

(i) Summary information about any research, embryo diagnostic procedure or innovative practice carried out under the licence in the last year, indicating the current status of the project (ongoing, suspended, finalised etc) and including any matters required as part of any approval given;

(ii) summary information about any complaint formally laid by a participant; and

(iii) summary information on required counselling services including, in numerical terms, counselling sessions provided during the previous year, the number of individual participants and couples counselled, the proportion counselled of those undergoing treatment or donating, and any other counselling activities carried out on behalf of the licensee.

Note: Direction 9.2 requires information about all changes to routine laboratory or clinical procedures approved by the person responsible during the year to be provided to the Commissioner of Health with the Annual Report.

Annual Reporting by Exempt Practitioners

*2.31 Exempt Practitioners must submit an Annual Report to the Commissioner of Health by 31 July each year, relating to the previous financial year from July 1 to June 30. This Annual Report must include the following information:

Exemption number; and

the number of intra-uterine insemination procedures carried out under the Exemption during the year, with a breakdown as shown in the tables below—

(a) Source of semen and use of ovulation induction.

Source of Semen	Ovulation Induction	# IUI procedures
donor	-nil	
	-clomiphene only	
	-with gonadotrophins	
husband/partner	-nil	
	-clomiphene only	
	-with gonadotrophins	
	Total # IUI procedures	

(b) Showing number of sacs on initial ultrasound and (plurality of ongoing pregnancy (OP)) by ovulation induction method.

# Sacs or plurality of OP	Ovulation Induction			Total
	nil (# OP) # initial US	clomiphene only # initial US (# OP)	with gonadotrophins # initial US (# OP)	# initial US (#OP)
1				
2				
3				
4				
>4				
Total pregnancies initial US and (OP)				

Note: Examples to assist with the completion of this table may be found in the Guidelines to this section of the Directions.

This is the sole requirement for Annual Reporting by Exempt Practitioners at this time.

NOTIFICATION OF CHANGE IN CIRCUMSTANCES OR DETAILS OF LICENSEE

2.32 The Licensee must notify the Commissioner of Health (COH) in writing if any of the following events occur—

2.32.1 Insolvency Events

(i) if the Licensee is a corporation, it becomes insolvent for the purposes of Section 922(1) of the Corporations Law;

(ii) if the Licensee is an incorporated association, any action is commenced pursuant to Section 31 of the Associations Incorporation Act 1987 or otherwise to wind up the association;

(iii) if the Licensee is a natural person, he or she becomes insolvent within the meaning of Section 922(3) of the Corporations Law;

(iv) if the Licensee is a firm—

a. an event specified in paragraph 2.32.1 i, ii, or iii occurs with respect to any member of thefirm or firm;

b. any action is commenced pursuant to Section 46 of the Partnership Act 1895 or otherwise to dissolve the firm.

2.32.2 Change in Constitution of Board/Firm/Trust

(i) if the Licensee is a body corporate, there is any change proposed or any change occurs in the constitution of the board of directors;

(ii) if the Licensee is a firm there is any change proposed or any change occurs in the membership of the firm;

(iii) if the Licensee is a trustee of—

A. a unit trust, there is any change proposed or any change occurs in—

a. the number of units on issue in the trust

b. the rights that attach to any units on issue or

c. the holders of the units on issues

B. a discretionary trust, there is any change proposed or any change occurs in—

a. the class of beneficiaries who may benefit under that trust

b. the appointor, controller or guardian of that trust.

2.32.3 Change of Control

If the Licensee is a body corporate

(i) there is any change in control of the body corporate

(ii) a takeover bid (as that term is defined in Section 9 of the Corporations Law) is made or announced with respect to all or any of the shares on issue in the Licensee.

2.32.4 Investigation

If an investigation is commenced pursuant to Section 13 of the Australian Securities Commission Act or otherwise to investigate the affairs or any of the affairs of the Licensee.

2.32.5 Change in Management Personnel, or Premises

Any change is proposed or any change occurs in management personnel or premises, at the licensed premises.

Without limiting the generality of this requirement, changes to be notified include any significant periods of absence of the person responsible from the licensed premises and change of Medical Director, in accordance with Direction 2.36.

2.32.6 Litigation or Arbitration Proceedings

(i) if the Licensee, or if the Licensee is a body corporate if any director, secretary or executive officer, or if the Licensee is a firm if any of its members, is prosecuted for an alleged breach of any Commonwealth or State legislation

(ii) if any judgement or award is entered against the Licensee or any member in an amount exceeding $50 000 or any officer in an amount exceeding $10 000.

2.32.7 Change in Business

The Licensee proposes to cease or ceases to carry on business either generally or at the premises described in the licence.

2.32.8 Change in Circumstances

Any change in the circumstances or details that the Licensee was required to provide in the Licensee's application for a licence or exemption.

2.33 Written notice to the COH must

(i) be sent to the COH in accordance with Direction 2.36, within 48 hours of the occurrence of the relevant event, and

(ii) contain sufficient information to enable the COH to assess whether the matters set out in Sections 29(4), 29(5) and 29(6), and Section 30(1) of the Human Reproductive Technology Act continue to be satisfied.

2.34 If the COH requests the Licensee to

(i) provide further particulars concerning the occurrence of any notified event; or

(ii) advise in writing, if any of the events specified in Directions 2.32.1-8 have occurred

the Licensee must immediately provide the COH with a written response containing such further particulars or particulars as to the occurrence of any event (as appropriate).

REQUIRED NOTIFICATION OF CHANGES TO PATIENT INFORMATION AND CONSENT FORMS

2.35 The person responsible must notify the Council of any change to a patient information sheet or consent form, or of the introduction of a new patient information sheet or consent form, by forwarding a copy of the new or amended sheet or form, permanently annotated with the date and version, to the Executive Officer of the Council, at or before the time the new or amended sheet or form is introduced.

METHOD OF REQUIRED NOTIFICATION

2.36 Notifications called for by directions 2.32.5, 2.34, 2.35 and 9.2 shall be given only by prepaid registered post or prepaid certified mail, addressed to:

Executive Officer
Western Australian Reproductive Technology Council
189 Royal Street, East Perth WESTERN AUSTRALIA 6004
OR such other address as may be notified to you.

SECTION 3: CONSENT

Part 3, Division 2 of the Act.

CONSENT FOR KEEPING OR USE OF GAMETES, ANY EGG IN THE PROCESS OF FERTILISATION OR ANY EMBRYO

*3.1 The person responsible must ensure that the required consents are given in relation to the use or storage of any gametes or embryo under a licence.

Limitations to consent for keeping any gametes or any embryo

3.2 Subject to Direction 6.5, the person responsible must ensure that any consent to store gametes is renewed every 5 years.

*3.3 The person responsible must ensure that no consent is given for a use not permitted under the Act, including the use of gametes of a person known to be dead.

WHO MUST GIVE CONSENT TO AN ARTIFICIAL FERTILISATION PROCEDURE

*3.4 The Act states that no artificial fertilisation procedure shall be carried out in a body, other than the body of a living woman who specifically consents to the procedure. Any person to whom the licence applies proposing to carry out an artificial fertilisation procedure must ensure that—

prior to an IVF procedure effective consent is given by the recipient's husband or de facto partner;

prior to an AI procedure, effective consent is given by the recipient's husband or de facto partner, if any; and

any other person required under the Act to give effective consent has done so.

*3.5 Prior to the donation of gametes or any embryo for an artificial fertilisation procedure any person to whom the licence applies overseeing such a donation must ensure that effective consent is given by the gamete provider, and that the gamete provider's current husband, wife and/ or de facto partner, if any, also gives effective consent to the donation.

*3.6 Any person to whom the licence applies or Exempt practitioner who proposes to use or direct the use of donor gametes or any donor embryo in an artificial fertilisation procedure must ensure that the husband, wife or de facto partner of the recipient has given effective consent.

CONSENT IN SPECIAL CIRCUMSTANCES

Consent to allow an embryo to succumb

3.7 Where each person who has the right to decide how an embryo is to be dealt with or disposed of gives effective consent for it to be allowed to succumb, the person responsible must ensure that the embryo is allowed to succumb.

Consent for innovative procedures, experimentation or diagnostic testing

3.8 The person responsible must ensure that a separate consent is given to each procedure, diagnostic test or experiment that is subject to the approval of Council.

Consent for the use of donor semen in special circumstances

*3.9 Any person to whom the licence applies or Exempt practitioner who proposes to use semen of a donor in an artificial fertilisation procedure or direct such a use of that semen, must ensure that the donor is aware of section 6 of the Artificial Conception Act 1985, unless the donor has already specifically consented to the use of his semen in such a circumstance.

Note: Direction 2.35 refers to notification of changes to patient consent forms or information sheets.

SECTION 4: INFORMATION

Part 3, Division 2 of the Act, section 22 in particular.

INFORMATION TO BE PROVIDED PRIOR TO CONSENT

*4.1 Prior to participants giving effective consent to any artificial fertilisation procedure, the person responsible must ensure that they are given oral explanations supported by relevant written material in a form approved by Council, including:

- information about the effects of the consents given, and the ability to place conditions and to vary or withdraw consents;
- accurate, objective information about the options that may be elected during treatment and the likely and relevant success rates for the procedure (national and for the clinic in question, as well as what is likely for the couple concerned);
- the potential risks, side effects, longer term outcomes, and limitations to current knowledge, for the participants and any child born;
- information about the Registers being kept for the purpose of monitoring and evaluating the procedures undertaken, including evaluation of the safety of those procedures in both the short and the long term, and limitations to the research uses of the Registers, namely—

  the only research done will involve linkage to existing public health data bases and will be bona-fide medical and public health research, that follows the stringent guidelines set by the Health Department's Confidentiality of Health Information Committee (CHIC);

there will be no publication of information that identifies any individual; and

in the event that a legitimate need for further medical or public health research arises, approved by CHIC on the advice of the Reproductive Technology Council, any consent requested for any further involvement in research may be refused;

- information about the status of any innovative procedure being consented to, with its likelihood of success, the potential risks and side effects and longer term outcomes, known and unknown, for the participants and any child born;
- information about counselling, including—

  counselling requirements and entitlements under the Act;

  the availability of counselling through the licensed practice;

  that counselling service is provided to assist decision-making and provide emotional and therapeutic support, such as grief/loss counselling; and

  encouraging counselling from an 'approved counsellor'; or
- information that the Act does not permit the use of gametes in an artificial fertilisation procedure where the provider of the gametes is known to be dead.

ADDITIONAL INFORMATION TO BE GIVEN IN RELATION TO THE USE OF DONATED REPRODUCTIVE MATERIAL

*4.2 Prior to consent being given to donation or use of donated human reproductive material, the person responsible must ensure that all donors and recipients are given oral explanations, supported by relevant written information in a form approved by Council, including information:

- drawing attention to the Artificial Conception Act 1985, in particular to the effect of sections 6 and 7 of that Act in relation to semen donation and section 60B of the Family Law Act;
- where a donor consents to use by a woman who does not have the consent of a husband or de facto partner, information about uncertainty in the application of the Artificial Conception Act 1985 or Family Law Act;
- about the Donor Register and inclusion of information about biological parentage, and access to non-identifying information under the Human Reproductive Technology Act 1991 to children born and to donors;
- about the possibility of developments in policy and legislation making identifying information about their biological parentage available to children of donors;
- about the medical, social (rearing) and secrecy implications in relation to donation and the rearing of donor children.

SECTION 5: ASSISTANCE WITH DECISION MAKING AND COUNSELLING

Section 22 of the Act.

ASSISTANCE WITH DECISION MAKING AND COUNSELLING IN RELATION TO IVF/GIFT

5.1 In accordance with sections 18 (2)(a), 22 (7)(a) and 33 (2)(c) of the Act, the Licensee must ensure that all couples undergoing an IVF procedure have access to an 'approved counsellor'.

(See the guidelines for standards and process of recognition of 'approved counsellors')

5.2 The Licensee must ensure that the cost of at least one hour with an 'approved counsellor' for each IVF cycle begun, as well as one extra hour when the decision is being made to withdraw from further IVF treatment, is included in the overall cost of treatment.

The cost of counselling is transportable by arrangement between the couple and the person responsible when a couple chooses to see an 'approved counsellor' outside the licensed practice.

No discount is available to a couple that chooses not to use required counselling.

5.3 The Licensee must ensure that counselling is provided routinely (see the guidelines), and that each couple proposing to undergo an IVF procedure is provided with information about their entitlements. The person responsible must ensure participants are aware that, although strongly encouraged, it is not mandatory to undergo counselling, and that they may choose, in consultation with the clinic counsellor, how and when to take up their entitlements.

5.4 The Licensee must ensure that each counsellor who carries out required counselling is not a staff member directly involved with the artificial fertilisation procedures being undertaken, and that the role of any counsellor who is providing required counselling is clearly separated from any assessment of the suitability of participants to undergo treatment.

Separation of the role of the counsellor from the assessment process

Directions 7.2 and 7.3 set out the responsibility for assessment of eligibility for treatment and the importance of separation of the role of the counsellor from the assessment process.

ASSISTANCE WITH DECISION MAKING AND COUNSELLING IN RELATION TO GAMETE DONATION

Anonymous donation

*5.5 The holder of a Storage licence under which there is collection and storage of semen must ensure that all semen donors are provided with a list of 'approved counsellors', and adequate

information, in a form approved by Council, that encourages donor preparation by including assistance with decision making; clarifying the impact of becoming a donor; and about the medical, social and secrecy implications of donation.

5.6 The Licensee must ensure that all donors of eggs or embryos are provided with adequate information, in a form approved by the Council, that encourages donors to seek assistance with decision making and counselling from an 'approved counsellor', that sets out the availability of counselling through the licensed practice and their entitlements to it, and covers medical, social and secrecy implications of the donation.

Egg or embryo donors are entitled to one hour with an 'approved counsellor' within the cost of treatment. The Licensee must ensure that counselling is provided as a routine part of the treatment of infertile donors. The licensee must also ensure that the information provided to donors is designed to strongly encourage participants to take advantage of counselling.

*5.7 The Licensee must ensure that all recipients of donated human reproductive material are provided with comprehensive information, in a form approved by Council in accordance with Directions 2.35 and 2.36, which is designed to strongly encourage at least one session with an 'approved counsellor' to assist in their decision making and cover medical, social and secrecy implications of rearing a child born after donation.

Known donors

*5.8 Prior to any artificial fertilisation procedure where a donor is known to the recipients, the Licensee must ensure that the donor and recipient involved, and their spouses and/or de facto partners (if any), have had at least one session with an 'approved counsellor', to assist in their decision making and cover all relevant medical, social and secrecy implications of the donation. The Licensee must also ensure that the participants are provided with adequate and relevant written information, in a form approved by Council in accordance with Directions 2.35 and 2.36.

Telephone counselling may be acceptable, where criteria for providing telephone counselling have been approved by the Council.

SECTION 6: USE AND STORAGE OF GAMETES AND EMBRYOS

Sections 22 - 26 of the Act.

IMPORT AND EXPORT OF DONATED MATERIAL

*6.1 Any person to whom the licence applies must not accept from outside the State (import) for use in an artificial fertilisation procedure donated gametes, or embryos where donation of human reproductive material has been involved, if all the information that would be required under the Act for the Donor Register, had the donated human reproductive material been collected in this State, is not available to them.

The person responsible may apply to the Council for an exception to Direction 6.1, on compassionate grounds.

*6.2 Any person to whom the licence applies must not allow the export from the State for use in an artificial fertilisation procedure of donated gametes or embryos where donation is involved, where the export is to a person not approved by the Council, and where there is no written undertaking by that person to provide the person responsible with information that would be required for the Donor Register, had the donated material been used within this State.

Where the undertaking to provide information is not complied with within a reasonable time and without good reason the approval of Council to the export may be withdrawn.

Note: Appropriate forms for seeking Council approval are set out in the Guidelines.

*6.3 Any person to whom the licence applies may accept gametes or any embryo from outside the State if no donation of human reproductive material has been involved and the gametes or embryo are to be used in the treatment of the person or persons who provided the gametes, or if the material is to be used in a research project that has the specific approval of the Council to proceed.

6.4 A person to whom the licence applies must not permit or facilitate the export from this State of an embryo for a purpose other than would be allowed under the laws of this State.

MAXIMUM PERIOD OF STORAGE OF GAMETES

*6.5 The Licensee must ensure that gametes are not stored for longer than 15 years, and ensure that consent to storage is renewed at least every five years during this period.

However, where the stored gametes are to be used in treatment of the gamete provider or for research, the person responsible may apply in writing to the Reproductive Technology Council for an extension of this 15 year limit.

DEALING WITH IMPENDING EXPIRY OF PERMITTED STORAGE PERIODS OF EMBRYOS GENERALLY

6.6 The person responsible must ensure that—

(i) all persons with the right to make a decision about an embryo in storage are notified and their instructions sought for dealing with the embryo no later than six months prior to the expiry of the permitted storage period;

(ii) notifications must be in accordance with the confidentiality provisions of the Act and any specific requirements given by the person about contacting them, and such that information about the person's treatment is not divulged.

Actions taken to notify persons and seek their instructions may include-

writing to the last known address; and

telephoning and contacting the person's general practitioner or any other suitable third party.

(iii) application to the Council for an extension of the permitted storage period by these persons must be in accordance with Form 8 in Appendix 10 of the guidelines.

DEALING WITH IMPENDING EXPIRY OF THE PERMITTED STORAGE PERIOD OF EMBRYOS WHERE THE LICENSEE HAS NO RELEVANT INSTRUCTIONS FROM THE COUPLE

6.7 The person responsible must notify the Council in writing at least two weeks prior to the expiry of the permitted storage period of embryos in the possession of the Licensee where:

the person responsible has been unable to contact the couple who stored them; or

the person responsible has been in contact with the couple, but does not have—

written consent to allow the embryos to succumb; or

notification from the Council that an extension has been granted or refused.

Applications for extension of the permitted storage period must be in accordance with Form 9 in Appendix 10 of the guidelines, and include—

the names and ID codes of participants;

date of storage of the embryos and date of expiry of permitted storage of these embryos;

the number of embryos affected;

the nature of any contact between the clinic and the participants regarding expiry of the permitted storage period.

SECTION 7: ELIGIBILITY AND ASSESSMENT

Divisions 2 & 3 of Part 3 of the Act.

MINIMUM AGE FOR DONATION

*7.1 The licensee must ensure that gametes or any embryo used in an artificial fertilisation procedure are not donated by a person aged under 18 years.

ASSESSMENT OF ELIGIBILITY FOR TREATMENT

7.2 The Act specifies criteria that persons to whom the licence applies must consider before an IVF procedure may be carried out. Although the decision to treat may be based on input from a variety of persons to whom the licence applies, the Licensee must ensure that the medical practitioner treating the patient makes the final decision as to the eligibility of any participant on both legal and medical grounds, and should maintain a record of the reasons for this decision in accordance with the standards of good medical practice.

7.3 The Licensee must ensure that the role of the clinic-based counsellor is clearly separated from the assessment process. In general if the counsellor is concerned by information provided in confidence, he/she should obtain the consent of the participant before discussing this with the medical practitioner.

However, there may be situations where the duty of care, such as to a child who may be born as a result of the treatment to be undertaken, may override the requirement for separation of counselling and assessment and where, based on standards of good professional practice, the counsellor should advise the medical practitioner of the concerns and suggest that a second opinion be sought about matters that may affect the eligibility of the participant.

SECTION 8: SPECIFIC CLINICAL PRACTICE ISSUES

Part 3 of the Act.

PRACTICE IN RELATION TO DONATION

Limits to the number of offspring a donor may have

*8.1 The Licensee must ensure that for each donor of gametes there are no more than five known donee families, including families that may be outside Western Australia.

However, where embryos have been developed using donated gametes and the couple with the right to make this decision wish to donate them, and where the donation may result in this maximum being exceeded, the person responsible may apply in writing to the Council for an extension to the limit.

Known donors

*8.2 Where a prospective donor is known to the recipient(s) and donated gametes or embryo(s) to be used in the artificial fertilisation procedure are not to be stored and quarantined prior to use,

the person to whom the licence applies must not allow the artificial fertilisation procedure to take place earlier than 6 months after the initial agreement between the parties to the procedure, and must ensure that the information given to the recipient(s) includes information about the fallibility of an HIV test under such circumstances.

(See Direction 5.8 regarding counselling requirements under these circumstances)

No deliberate confusion of biological parentage

*8.3 Any person to whom the licence applies who is directly involved in carrying out an artificial fertilisation procedure must not allow multiple sources of eggs, sperm or embryos to be mixed in the procedure in such a manner as may create confusion as to the biological parentage of any child born.

OTHER PRACTICE ISSUES

Repeated ovarian stimulation

8.4 Any person to whom the licence applies must not allow collection of eggs where they are to be used in the development of embryos for the treatment of a couple who have, at that time, the right to make decisions about three or more stored embryos of the same biological parentage. However, if there are only one or two embryos of the same biological parentage in storage for that couple, a further egg collection may be carried out.

The person responsible may apply to the Council for an extension to this limit in exceptional circumstances.

No posthumous use of gametes

*8.5 Any person to whom the licence applies must not knowingly use or authorise the use of gametes in an artificial fertilisation procedure after the death of the gamete provider.

An embryo only to be developed with a view to its future implantation

8.6 Any person to whom the licence applies must not develop, or authorise the development of an embryo, other than with a view to its future implantation in a particular woman, and the relevant consent should indicate this intention.

SECTION 9: APPROVAL OF LABORATORY AND CLINICAL PROCEDURES

Section 20 of the Act.

APPROVAL OF ROUTINE LABORATORY AND CLINICAL PROCEDURES

9.1 At the time of licensing:

the person responsible must ensure that all routine procedures which are to be followed are in accordance with criteria outlined in the guidelines, and documented in a detailed manual for which the approval of Council is obtained.

9.2 For any change or addition to approved routine clinical or laboratory procedures—

i) Council may:

grant its general approval; or

request further information to assist consideration of its approval for the change, and in the meantime it may or may not require the new practice to be withdrawn; or

refuse to grant general approval, require the new practice to be withdrawn, and suggest that an application be made for specific approval of the proposed change;

ii) the manual must be updated, and dated and approved by the person responsible, at or before the time the change is introduced;

iii) the manual must be provided to the Council at any time on request;

iv) Licensees must draw the Council's attention to all changes by way of a document accompanying their annual reports. Each reference must be by date of approval of the change by the person responsible and be accompanied by a copy of the page or pages from the manual showing by strikeout (for deletions) and underlining (for additions) the text of each such change. At this time Council will give its determination of the changes.

v) approval of the changes is not to be inferred from failure of the Council to respond;

vi) where there is any doubt as to whether or not the proposed change would be considered routine or innovative, the person responsible should ensure that the matter is raised with the Council prior to introduction of the change, by notification in accordance with Direction 2.36.

APPROVAL OF RESEARCH, INNOVATIVE PROCEDURES AND EMBRYO DIAGNOSTIC TESTS

9.3 For any proposed research, any clinical or laboratory procedure that may be considered innovative according to the criteria set out in the guidelines, or any diagnostic procedure involving an embryo, the person responsible must ensure that the specific approval of Council is sought, in accordance with the guidelines, and the research, innovative laboratory or clinical procedure, or embryo diagnostic procedure must not be implemented without this approval.

9.4 Where approval is sought from Council for any embryo research or diagnostic procedure to be carried out upon or with an embryo, the person responsible must ensure that the application for approval gives evidence, as outlined in the guidelines, that this is intended to be therapeutic for that embryo, and unlikely to have any detrimental effect upon it.

SCHEDULE TO DIRECTIONS GIVEN BY THE COMMISSIONER OF HEALTH UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991:

FORMS FOR REPORTING TO THE REGISTERS

Form 1	Participant Identifying Information
Form 2	IVF Participant History

IVF Treatment cycle information:

Form 3a	Oocyte retrieval
Form 3b	Fertilisation
Form 3c	Embryo transfer
Form 4	Donor Information
Form 5	Donor Insemination Treatment Form
Form 6	Donor Identifying Information
Form 7	Recipient Identifying Information

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HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
IVF REGISTER

FORM 1 IVF PARTICIPANT IDENTIFYING AND DEMOGRAPHIC INFORMATION

This should be sent when requested by IVF Register staff. Where practicable it should be sent on computer disc, and in ASCII or other compatible format.
This is required only ***once*** for each participant (eg each woman and her husband or partner).

Participant ID Code ☐☐☐☐☐☐☐☐

Sex ☐

Surname _____

Given name _____

Other given name(s) _____

Maiden name (if applicable) _____

Any other previous surname (if applicable) _____

Date of Birth ☐☐ ☐☐ ☐☐ (Day Month Year)

Place of Birth WA ☐ Other State: specify _____

Other Country: specify _____

Occupation specify _____

Postcode of Residence ☐☐☐☐

Licensee number ☐☐☐

Has this participant undergone IVF treatment at another WA IVF clinic since 8 April 1993? **Y/N**

If so, at which clinic (Please specify)? _____

Please return to Research Officer, Reproductive Technology, Health Department of WA, 189 Royal Street, East Perth WA 6004 Ph: (08) 9222 4260 Fax: (08) 9222 4236 /March 1994

HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
IVF REGISTER

FORM 2 PARTICIPANT HISTORY

This form should be completed only once for each person (Male and Female), either at the beginning of their first ever IVF treatment cycle in this clinic (IVF as defined by the HRT Act) or the first undertaken there since the HRT Act came into operation.

1. OBSTETRIC HISTORY

	Female	Husband/Partner
Participant ID Code		
For husband/partner this refers to any pregnancy/birth/child he fathered		
Do both partners have the same history? (Y/N)	*(if yes, complete for female only)*	
Gravida		
Parity		
Number of children of current relationship		
Duration of Infertility (years) (this couple)		

Are these person(s) involved in an IVF procedure for treatment of their *own* infertility? Y/N

If *NO,* is the invlovement

as an egg donor? Y/N

or

to avoid having a child with a genetic abnormality or disease? Y/N

or

for some other reason ? Y/N *(please specify)*

Is this form being completed at time of the first ever IVF treatment cycle for this couple at this clinic? Y/N

(Note: "no" implies this couple has had IVF treatment at this clinic prior to the Human Reproductive Technology Act ie prior to April 1993)

Licensee number

NOTE: form continues over page

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2. CAUSE OF INFERTILITY (at time of first IVF treatment cycle in this clinic)

2.1 Female

Participant ID Code ☐☐☐☐☐☐☐☐

2.1.1. Female factors *Tick all factors involved in infertility*

None ☐ *(if none go to section 2.2)*

Unknown ☐

Egg/ovary ☐

Tubal occlusion/absent tubes Unilateral ☐ Bilateral ☐

Tubal factors other than occlusion ☐

Cervical factors ☐

Uterine factors ☐

Other ☐ specify _____

2.1.2 Female causes *Tick all causes for female factors*

			mild	moderate	severe
☐	Pelvic adhesions (post operative)	severity	☐	☐	☐
☐	PID (including TB)	severity	☐	☐	☐
☐	Endometriosis	severity	☐	☐	☐
☐	Congenital anomaly	specify _____			
☐	Ectopic pregnancy				
☐	Antibodies				
☐	Endocrine				
☐	Sterilisation				
☐	External				
☐	Idiopathic/Unknown				
☐	other	specify _____			

2.2 Male

Participant ID Code Husband/Partner ☐☐☐☐☐☐☐☐

2.2.1 Male factors *Tick all factors involved in infertility*

None ☐

Unknown ☐

Azoospermia ☐

Oligospermia ☐

Asthenozoospermia ☐

Teratozoospermia ☐

Sexual and Ejaculatory dysfunction ☐

Other ☐ specify _____

2.2.2 Male causes *Tick all causes for male factors*

			mild	moderate	severe
☐	Testicular damage	severity	☐	☐	☐
☐	Male accessory gland	severity	☐	☐	☐
☐	Antibodies	severity	☐	☐	☐
☐	Congenital anomaly	specify _____			
☐	Varicocele				
☐	Endocrine				
☐	External				
☐	Sterilisation				
☐	Idiopathic/Unknown				
☐	other	specify _____			

HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
IVF REGISTER

TREATMENT CYCLE INFORMATION

FORM 3A OOCYTE RETRIEVAL

This form should be completed for each oocyte retrieval cycle commenced. Please complete using text, numbers or ticks as appropriate.

1. Cycle Details

Oocyte retrieval code R [ ][ ][ ][ ][ ][ ][ ][ ][ ] Date cycle commenced [ ][ ] day [ ][ ] month [ ][ ] year

Participant ID code Female [ ][ ][ ][ ][ ][ ][ ][ ] Licensee number [ ][ ][ ]

2. Medication During the Treatment Cycle leading to egg retrieval

Natural Cycle (ie no ovulation induction) [ ]

	Drug	Total Dose	Nmbr of Days
Down Regulation			
Stimulation (including ovulation trigger)			

General Anaesthetic Used [ ] Antibiotics [ ] Other (*specify*) _____ [ ]

3. Oocyte Retrieval

Cancelled [ ] Laparoscopy [ ] Trans vaginal Ultrasound [ ] Other (*specify*) _____ [ ]

Number of eggs retrieved [ ][ ]

Number of eggs for experiments [ ][ ]

Number of eggs discarded [ ][ ]
(prior to fertilisation)

Recipient fertilisation code(s)
(use only if eggs donated)-

Number of eggs donated [ ][ ]

F [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

F [ ][ ][ ][ ][ ][ ][ ][ ][ ]

4. Ovarian hyperstimulation syndrome

None [ ] Mild [ ] Moderate [ ] Severe [ ]

Complete a Fertilisation form for each unique fertilisation (including GIFT) ie each fertilisation can have only one source of eggs and one source of sperm.
If the cycle was cancelled or there was no oocyte retrieval do not complete any other forms

Please return to Research Officer, Reproductive Technology, IIealth Department of WA, 189 Royal Street, East Perth WA 6004 Ph: (08) 9222 4260 Fax: (08) 9222 4236 /March 1994

IVF REGISTER

TREATMENT CYCLE INFORMATION

FORM 3B GIFT OR OOCYTE FERTILISATION

This form should be completed for each unique fertilisation, including GIFT, attempted: use text, numbers or ticks as appropriate.

1. Cycle Details

Oocyte fertilisation code F | | | | | | | | | | Oocyte retrieval code R | | | | | | | | | |

Licensee number | | | Date cycle commenced | | day | | month | | year

Participant ID code Female on whose behalf the embryos are being developed | | | | | | | | |

2. Sperm Preparation

Husband/partner sperm used ☐ ID code of husband/partner | | | | | | | | |

or ***and***

Donor sperm used ☐ ID code of donor ***(if used)*** | | | | | | | | |

Storage licensee number (collector of donor sperm):

(specify if relevant) _____ | | |

surgery (eg Epididymal aspiration) ☐

washing only ☐

gradient ☐

swim up ☐

chemical stimulation ☐ specify _____

other ☐ specify _____

Micro manipulation used (Y/N) ☐ specify _____

3. Fertilisation

Number of eggs replaced at GIFT ☐ Had these eggs been exposed to sperm in a previous fertilisation attempt? (Y/N) ☐

Total number of eggs exposed to sperm in vitro | | Number of eggs ***not*** fertilised | |

4. Embryo dispersal**

Number of embryos for: fresh transfer | | donation | | freezing | |

Number of embryos discarded: abnormal or degenerate | | surplus normal | |

Note:**Where donor sperm embryos are involved, information reported to the storage licensee at this time must include details of any embryo storage. Any subsequent transfer of these embryos must also be reported to the storage licensee.

5. GIFT DETAILS *To be filled in where **transfer** is **GIFT only***

5.1 Medication following GIFT

NONE ☐

	Drug (proprietary name)	Total dose	# days
Luteal Support			
Pregnancy Support			

5.2 GIFT outcome *by 20 weeks, tick one:*

No clinical pregnancy ☐ Ongoing clinical pregnancy ☐

Early pegnancy loss-

ectopic ☐ spontaneous abortion ☐ blighted ovum ☐

missed abortion ☐ T.O.P. (induced abortion) ☐

Other ontcome ☐ (*specify*)_____

5.3 Other medication not already recorded (eg in preparation of participant for donor egg transfer): Please specify ***drug(s)*** used, ***total days*** and ***total dose*** used

NOTE: *An embryo transfer form (3C) must be completed for each fresh or subsequent frozen embryo transfer*

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HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
IVF REGISTER

TREATMENT CYCLE INFORMATION

FORM 3C EMBRYO TRANSFER

This form should be completed for each Embryo transfer commenced, either a fresh embryo transfer (as part of an IVF ET procedure) or an FET. Please complete using text, numbers or ticks as appropriate.

1. Cycle Details

Embryo transfer code T | Date cycle commenced day month year

Oocyte fertilisation code F | F

Participant ID code Female | Husband/Partner

Licensee number

2. Embryo Transfer Procedure *(tick may be more than one)*

Cancelled | IVF+GIFT | FET (all)

IVF ET | all fresh tubal transfers | Other | specify

3. Medication leading up to and following procedure

NONE

	Drug (proprietary name)	Total Dose	Nmbr of Days
Down Regulation			
(Complete for FET only)			
Stimulation			
(Complete for FET only)			
Luteal Support			
Pregnancy Support			

General Anaesthetic Used | Antibiotics | Other *(specify)*

4. Frozen Embryos *(if none used go to section 5)*

(tick either) Donor embryos used | ***or*** Own frozen embryos used | ***(incl. donor egg embryos here)***

Number of embryos thawed | Number of thawed embryos unsuitable for transfer

5. Embryo Transfer

Number of embryos transferred**

**Any transfer (fresh or frozen) involving donor sperm embryos should be reported to the Storage Licensee. Information should include the number of donor sperm embryos replaced, the number still in storage, and the outcome of the transfer at 20 weeks.

6. Final Outcome *by 20 weeks (select only one)*

No clinical pregnancy | Ongoing clinical pregnancy

Early pegnancy loss-

ectopic | spontaneous abortion | blighted ovum

missed abortion | T.O.P. (induced abortion)

Other outcome *(specify)*

HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
DONOR REGISTER

FORM 4 DONOR INFORMATION

This form must be completed ONCE for each donor who has achieved one or more ongoing clinical pregnancies

Donor code ☐☐☐☐☐☐☐☐☐☐

Sex male ☐ female ☐

colour of hair _____

colour of eyes _____

complexion _____

build _____

height (cm) _____

marital status never married ☐ married ☐ de-facto ☐
divorced ☐ separated ☐ widower ☐

occupation _____

religion (if any) _____

country of birth _____

ancestry (by ethnicity of grandparents)
mother:
mother _____
father _____
father:
mother _____
father _____

highest education level attained _____

personal and/or professional interests _____

number of existing children
genetic children (other than donor) male ☐☐ female ☐☐
total donor children ☐☐

Details of personal health history
(Summarise from the declarations made at the time of donation, in accordance with RTAC guidelines)

_____

Details of family history
(Summarise from the declarations made at the time of donation, in accordance with RTAC guidelines)

_____

Donor's blood group ☐☐ Rh ☐ Other antibodies _____

Reason for participating in donor program _____

An optional personal statement of about 100 words may be attached.

Please return to Research Officer, Reproductive Technology, Health Department of WA, 189 Royal Street, East Perth WA 6004 Ph: (08) 9222 4260 Fax: (08) 9222 4236 /March 1994

HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
DONOR REGISTER

FORM 5 DONOR INSEMINATION TREATMENT

This form must be completed by the Storage Licensee who collected the sperm for each DI treatment.

Donor code ☐☐☐☐☐☐☐☐

Recipient code ☐☐☐☐☐☐☐☐

Date of procedure ☐☐ ☐☐ ☐☐
day month year

Sperm storage licence number ***(collector of sperm)*** ☐☐☐☐

Licensee or exemption number ***(user of sperm)*** ☐☐☐☐

Outcome of procedure by 8 weeks: ***(tick one)***

no clinical pregnancy ☐

very early pregnancy loss-

ectopic pregnancy ☐

spontaneous abortion ☐

blighted ovum ☐

missed abortion ☐

termination of pregnancy ☐

ongoing clinical pregnancy at 8 weeks ☐

other, specify _____ ☐

(if outcome unknown specify reasons): _____

If there is an ongoing clinical pregnancy ***or the outcome is unknown*** *then please fill out* ***DONOR INFORMATION FORM****.*

Please return to Research Officer, Reproductive Technology, IIealth Department of WA, 189 Royal Street, East Perth WA 6004 Ph: (08) 9222 4260 Fax: (08) 9222 4236 /March 1994

HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
DONOR REGISTER

FORM 6 SPERM DONOR: IDENTIFYING INFORMATION

This information should be sent to the Donor Register when requested by Register staff, for all sperm donors involved in an AF procedure, whether or not a clinical pregnancy was achieved. Where practicable it should be sent on computer disc in an ASCII file or other compatible format.

Donor code ☐☐☐☐☐☐☐☐

Surname _____

Given name(s) _____

Maiden name (if applicable) _____

Date of Birth ☐☐ ☐☐ ☐☐
day month year

Postcode of residence ☐☐☐☐

Licensee number ☐☐☐☐

Please return to Research Officer, Reproductive Technology, Health Department of WA, 189 Royal Street, East Perth WA 6004 Ph: (08) 9222 4260 Fax: (08) 9222 4236 /March 1994

HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
DONOR REGISTER

FORM 7 DI RECIPIENT IDENTIFYING INFORMATION

This information is required for each recipient of donor sperm for DI where there is an ongoing clinical pregnancy at 8 weeks. The information should be sent to the Donor Register when requested by Register staff, and where practicable it should be sent on computer disc in an ASCII file or other compatible format.

This form is to be completed and sent in by the practitioner carrying out the DI procedure

Recipient code | | | | | | | | |

Surname _____

Given name(s) _____

Maiden name (if applicable) _____

Date of Birth | | | | | | |
day month year

Postcode of residence | | | | |

Licensee or Exemption number | | | | |

Please return to Research Officer, Reproductive Technology, Health Department of WA, 189 Royal Street, East Perth WA 6004 Ph: (08) 9222 4260 Fax: (08) 9222 4236 /March 1994


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