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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

10667/3/93—1350

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Throughout these directions any reference to an embryo includes a reference to an egg in the process of fertilisation.

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

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INTRODUCTION TO THE DIRECTIONS.

The Human Reproductive Technology Act 1991 comes into operation on April 8 1993. This Act was passed through Parliament in response to the intense public concern expressed about potential implications of the new techniques in reproductive technology. Over the last decade medical intervention and research directed at alleviating infertility or reducing the risk of inherited genetic abnormalities has continued to expand rapidly.

The Act is intended to regulate and monitor this 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 to be regulated under the Act, which establishes a system of licensing for those practitioners undertaking the various procedures of reproductive technology.

The Act also establishes the Western Australian Reproductive Technology Council, for which one important task is to develop and maintain a Code of Practice that will provide guidance about the proper conduct of licensed activities. This Code is to consist of Rules, and guidelines intended to assist licensee in the keeping of the Rules. Council is instructed by the Act to consult with groups in the community with relevant expertise and appropriate interests, in the compilation and review of the Code, which is concerned with areas of practice that raise fundamental ethical and social questions, as well as addressing the efficacy of clinical or scientific practices. The Rules of the Code of Practice will only take effect after Parliamentary scrutiny and approval, and Council will keep it under regular review, to ensure that it continues to give current guidance to the licensees and to achieve the objectives of the Act.

The Act covers IVF, GIFT and donor insemination and imposes new obligations upon those offering these treatments. Licensees must provide to participants access to counselling and substantial information about the procedures being undertaken. They must also provide information on procedures undertaken and their outcomes to two new registers - a Public Health IVF Register and a Donor Register.

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 on this register has been provided for under the Act, as this information may be of medical or social significance in the future.

As the Act is to come into operation at a time during which Parliament is not sitting, the standards that must be met by licensees in the short term will be those set by the Act itself, and those set out in these directions from the Commissioner of Health. The Act contains a number of principles that must be embodied in the Code of Practice or, until that time, may be referred to in directions. These directions, therefore, are issued on the advice of the council and must be complied with by the licensees until revoked or until the Code of Practice, with Parliamentary approval, prevails. Draft guidelines for licensees have also been developed by the Council, and these are intended to serve the same purpose as the guidelines that will make up Part II of the Code of Practice, that is assist in compliance with the directions.

In the framing of these 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 to individuals and to society.

It is recognised that in some cases there may be conflict between some of these important considerations. In attempting to resolve this conflict 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 ensuring that the exploitation of people, at a time when they are vulnerable, does not occur. It is assumed that all those conducting treatment and research in reproductive technology will observe the standards and requirements of good clinical and scientific practice.

Prior to the coming into operation of the Code of Practice, however, these directions will also serve as a useful consultation document upon which interested members of the community may comment. It is the intention of the Council that a draft Code of Practice will be laid before Parliament in accordance with section 16(2) of the Human Reproductive Technology Act, in the 1993 Spring session.

Your comments may be addressed to:

The Western Australian Reproductive Technology Council
c\o the Executive Officer
189 Royal Street
EAST PERTH 6004.

Phone: (09) 222 4260
Fax: (09) 222 4236

SECTION 1: PERSONNEL, PREMISES and MINIMUM STANDARDS OF PRACTICE

WHAT STANDARDS OF PRACTICE, PERSONNEL AND PREMISES ARE REQUIRED FOR A PRACTICE LICENCE?

1.1 *For a Practice Licence that authorises IVF procedures standards for practice, personnel and premises set by the Reproductive Technology Accreditation Committee (RTAC) and the National Association of Testing Authorities (NATA) are the minimum standards to be maintained, with the additional requirement for an "approved counsellor" to be available, as set out in Part 5 of the directions, and any other matters as required by the Code of Practice or directions from the Commissioner.*

1.2 *For a Practice Licence that authorises only artificial insemination and related research, the person responsible, who has the responsibility for all aspects of the procedures to be carried out under the licence, must be a currently registered medical practitioner.*

WHAT ARE THE REQUIRED STANDARDS FOR PRACTICE, PERSONNEL AND PREMISES FOR A STORAGE LICENCE?

1.3 *For a Storage Licence under which collection and storage of sperm for artificial fertilisation procedures involving donation, and\or the storage of eggs or embryos are to be undertaken, as a minimum any standards set by RTAC/NATA for practice, personnel and premises apply, and the staff must include a medical practitioner.*

1.4 *For a Storage Licence under which donor sperm to be stored is not collected by the licensee, or sperm collected is for artificial fertilisation procedures not involving donation, standards for practice, equipment, staff and facilities should be at the discretion of 'the person responsible', and comply with those of good medical practice and all requirements of the Act, the Code of Practice and any directions from the Commissioner of Health.*

WHAT STANDARDS APPLY 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 this registration, and an undertaking to follow the Code and directions, must be given at the time of application for the exemption, as required by the prescribed application form.*

WHEN SHOULD A LICENSEE APPLY FOR RENEWAL OF A LICENCE?

1.6 *A licensee must apply for renewal of a licence no later than three months before expiry of a current licence.*

SECTION 2: RECORDS AND REPORTING

RECORD KEEPING:

Records to be kept by Practice licensees

2.1 *A **Practice licensee** must maintain complete records relating to any artificial fertilisation procedures carried out, as dictated by the Act and good medical practice and in sufficient detail at least also to allow compliance with reporting requirements of the Code of Practice or directions.*

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) and 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 (where known, and if unknown reasons why not).*

*2.3 *Any **licensee or Exempt practitioner** collecting and using semen for AIH not involving storage must keep adequate records as directed by good medical practice as to the use and outcome of any such procedures performed.*

Records on the use of donor semen by an Exempt practitioner

*2.4 *A **licensee or holder of an Exemption** must keep records of any use of donor semen in an artificial **fertilisation (AF) procedure**, with details of any semen samples collected or used, the identity of any recipient and outcome of each procedure (where known, and if unknown, reasons why not).*

Records about embryo storage

2.5 *A **Storage licensee** must record complete information on all embryos stored, with relevant consents that identify current rights to deal with and dispose of each embryo stored, and details of all use, disposal, transfer to another Storage licensee, Council approved experimentation or diagnostic testing involving these embryos, with dates, and outcome of any use (where known and if unknown, the reasons why).*

Duration of maintenance of records required by the Act or Code.

*2.6 *Any **licensee or Exempt practitioner** required by the Act, Code or directions to keep records must maintain these for at least 25 years.*

Communication of information with a referring doctor.

*2.7 *Any **licensee or Exempt practitioner** may communicate to a referring doctor information obtained by reason of this Act respecting the identity of any participant, donor, or child born as a result of any artificial fertilisation procedure, in accordance with the dictates of good medical practice.*

REPORTING TO THE PUBLIC HEALTH IVF REGISTER

Content

2.8 A Practice licensee must transfer to the Public Health IVF Register the information about IVF participants and treatments specified in Forms 1-4 in the Schedule to these directions.

Timing and manner of transfer of information to the IVF Public Health Register

2.9 A Practice licensee must transfer the required information to the Public Health IVF Register at the following times:

(i) In the case of named identifying information about participants and their partners this shall be provided by March 30 of each year for all participants who have commenced a treatment during the previous calendar year.

(ii) All other details - non-identifying information about participants and treatment details for all treatment cycles- must be sent to the Register within the following time frame:

for treatment commenced between January 1 and April 30 details must be reported before September 30;

for treatment commenced between May 1 and August 31 details must be reported before January 31; and

for treatment commenced between September 1 and December 31 details must be reported before May 30.

2.10 A Practice licensee must transfer the required information to the Public Health Register in the following manner:

(i) in the case of identifying information this must be sent to the register in an electronic form in the format specified in Form 1 of the Schedule to these directions;

(ii) the remaining information is to be sent in the format indicated in Forms 2-3 of the schedule to these directions.

TRANSFER OF RESPONSIBILITY TO REPORT TO THE REGISTERS

2.11 In the event that a Storage licensee transfers stored gametes or any stored embryo to another Storage licensee, the responsibility to report all the information required by the directions to the Public Health IVF Register and/or the Donor Register remains with the original licensee, until he/she can evidence the transfer of this responsibility to the other licensee, including a written agreement by the other licensee to take over this responsibility.

2.12 Where a Storage licensee gives a written agreement to accept the responsibility for reporting to the Public Health IVF Register and/or the Donor Register, the responsibility to report to the Register transfers to him/her.

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

Content

*2.13 *Any **Storage or Practice licensee** or holder of an **Exemption** required by directions 2.15-2.20 to report to the **Donor Register** on each use of donated human reproductive material in an artificial fertilisation procedure, must report all the information detailed in Forms 4-7 in the Schedule to these directions, unless an exception under direction 2.14 applies, in the manner detailed in the directions or the guidelines.*

*2.14 *The information required to be supplied by a **licensee or holder of an Exemption** to the **Donor Register** does not include identity of the donor of any human reproductive material used-*

*i) in respect of the use of any **embryos** already in store at the time the Act comes into operation produced with donor gametes, 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 for the licence has not been able to trace 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 the use of any **donor gametes** already in store at the time the Act comes 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 these would be stored for treatment to provide her with a full sibling for an existing donor child, and*

(a) the person responsible for the licence has not been able to trace 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;

provided that at time of registration of the information that is required in relation to the procedure the reasons for non-inclusion of identity of the donor are provided.

Chain of reporting about the use of donor sperm

- **Reporting back to the Storage licensee about donor semen supplied by the Storage licensee**

*2.15 *Any **Exempt practitioner, Storage licensee or Practice licensee** using or dispensing donor semen that they have not themselves collected, but which has been supplied to them by a Storage licensee who collected the semen, must report to that Storage licensee, in a manner agreed to between themselves, information about the use and subsequent outcome of any semen provided to them by that Storage licensee. In cases of ongoing clinical pregnancy, the identity and date of birth of the recipient should be reported directly to the Donor Register.*

. **Reporting by the Storage licensee to the Donor Register about donor sperm collected by them**

2.16 *The Storage licensee who collects donor semen and dispenses it is responsible for reporting to the Register all relevant information about any use of this semen and outcome subsequent to this use, as required by these directions (2.13, 2.23, 2.24), unless this responsibility has been transferred to another Storage licensee (2.11, 2.12).*

. **Reporting directly to the Register when donor semen not supplied by a Storage licensee**

**2.17* *Any Exempt practitioner or Practice licensee using donor semen that has not been supplied to them by a Storage licensee must report to the Register direct, all the relevant required information about the donor, the recipient and the use of that semen and subsequent outcome of that use as required by these directions (2.13, 2.23, 2.24).*

Chain of reporting information about stored embryos

. **Embryos supplied by a Storage licensee**

2.18 *Any Practice licensee using embryos, including donor egg embryos or donor embryos, which have been supplied to them by a Storage licensee , must report to that Storage licensee, in a manner agreed to between themselves, details about the use in an artificial fertilisation (AF) procedure, and subsequent outcome of this use, including, for donor egg embryos or donor embryos the treatment cycle code and, in cases of ongoing clinical pregnancy resulting from treatment with donor egg embryo(s) or donor embryo(s), the identity and date of birth of the recipient.*

2.19 *A Storage licensee who stores donor egg embryos or donor embryos is responsible for sending to the Register all the relevant information about the use and outcome of use in AF procedures of these embryos, as required by these directions (2.13, 2.23, 2.24) unless this responsibility is transferred to another Storage licensee when the stored embryos are transferred (2.11, 2.12).*

. Reporting directly to the Register information about the use of fresh donor embryos

2.20 *Any Practice licensee using donor egg embryos or donor embryos in an AF procedure where storage was not involved must contact the Donor Register direct with information required by these directions (2.13, 2.23, 2.24).*

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 or deemed to be exempt under the Act, and provides evidence of exemption.*

**2.22* *The Storage licensee is responsible for following up information on outcomes of all stored reproductive material provided to exempt practitioners, Practice licensees or others legally allowed to carry out an AF procedure and may not continue to provide samples to any person who has failed to report this information within the required time, without good reason.*

Timing of transfer of information about donation to the Register

**2.23* *Any Storage or Practice licensee or Exempt practitioner required by the directions to send information to the Register about the use of donated human reproductive material is responsible for it being sent at the following times:*

(i) **Identifying information**

*For use of donated human reproductive material in a calendar year, in relation to all donors and **any recipients who appear to the licensee to have achieved an ongoing clinical pregnancy** (8 weeks) or for whom the outcome of the procedure was unknown, the **identifying information** required by the directions should be sent to the Register no later than **March 30** of the following calendar year;*

*(ii) **Non-identifying information***

*For any AF procedure involving the use of donated human reproductive material where it appears to the licensee that **an ongoing clinical pregnancy (8 weeks)** has been achieved as a result, the timing of reporting required **non-identifying information** to the Register is as follows:*

*For AF procedures carried out between January 1 and April 30, **no later than** September 30;*

*for AF procedures carried out between May 1 and August 31, **no later than** January 31;*

*and for AF procedures carried out between September 1 and December 31, **no later than** May 31.*

2.24 A **Licensee or Exempt practitioner must transfer 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, this must be sent to the Register in an electronic form, in the format as specified in Forms 6 and 7 of the Schedule to these directions;

*(ii) in the case of **identifying information** about recipients being sent by the holder of an Exemption, this may be sent to the Donor Register on Form 7 of the Schedule to these directions;*

(iii) the remaining information is to be sent on forms provided by the Commissioner of Health for this purpose or as specified in the Code of Practice or directions.

ANNUAL REPORTING

Timing of Annual Reporting:

*2.25 An **Annual Report**, relating to the previous calendar year, must be submitted by **all Practice licensees, all Storage licensees** who store eggs or embryos and **all Storage licensees** who collect and store donor semen, to the Commissioner of Health by June 30 each year, as specified in the Code of Practice or directions.*

Content of Annual reporting by Storage licensees -

. **about semen stored for donation:**

*2.26 An **Annual Report** submitted to the Commissioner of Health by a **Storage licensee** who collects and stores semen and must refer to all semen stored for donation, whether for use in an IVF procedure or DI, and must include any detail required by directions and be in the required format, including*

the following information:-

 # donors - frequencies by age, marital status, # times supplying samples for storage; total # DI treatments, # IVF treatments supplied;

For artificial insemination only:

(no more data to be reported by these licensees about donor IVF, as this will come from Practice licensees)

 # doctors, (with exemption numbers) and non-medical agents provided with semen for DI, and frequency supplied;
 # For each donor used this year-cumulative total clinical pregnancies, # families (over all years);
 # DI treatments outcomes unknown, reason why/frequencies by doctor, agent;
 # samples sent interstate/overseas for DI; and
details in summary of any relevant research carried out or facilitated by the licensee, and number and category of any complaints made by a participant through the formal complaints procedure set up by the licensee.

. **about egg or embryo storage**

2.27 *An Annual Report submitted to the Commissioner of Health by a Storage licensee who stores eggs or embryos must include any detail required by directions, and be in the required format, including the following information about embryo storage -*

 # embryos in storage at April 8 1993 (for the 1993 Annual Report only);
 # total, embryos in storage at December 31;
 # embryos thawed during the year, with # subsequently discarded and # used in treatment;
 # embryos and # batches of embryos transferred to another licensee or sent out of the State;
 # embryos donated from storage (prior to use in a treatment cycle); and
details in summary of any relevant research carried out or facilitated by the licensee, and number and category of any complaints made by a participant through the formal complaints procedure set up by the licensee.

Content of Annual reporting by Practice licensees

2.28 *An Annual Report submitted to the Commissioner of Health by a Practice licensee must include information to be detailed in directions, including information in summary of any relevant research carried out or facilitated by the licensee, and number and category of any complaints made by a participant through the formal complaints procedure established by the licensee.*

SECTION 3: CONSENT

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

3.1* *Consent is required to be given in relation to **any use or keeping of any gametes or embryo.*

Limitations to consent for keeping any gametes or any embryo.

3.2 *Consent to store gametes must be renewed every 5 years, up to a maximum of 15 years, although an extension to this may be granted by the Council in response to a written request, on a case by case basis where the gametes are stored other than for donation.*

**3.3* *No consent given by a gamete provider may include a consent for the posthumous use of the gametes.*

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. In addition -*

*prior to an **IVF procedure** consent must be given by the husband or partner of this woman;*

*prior to an **AI procedure**, the husband or partner of this woman must give consent; and*

any other person required by these directions to give consent, in particular circumstances, must do so.

3.5* *Prior to the **donation of gametes or any embryo for an artificial fertilisation procedure effective consent is required from any gamete provider, and their spouse or de facto partner, if any, must give effective consent to the donation.*

3.6* *Prior to the **use of donor gametes or any donor embryo in any artificial fertilisation procedure, the effective consents required include that of the spouse or de facto partner of the recipient.*

CONSENT IN SPECIAL CIRCUMSTANCES

Consent to allow an embryo to succumb

3.7 *Where each person who has the right to decide how it is to be dealt with or disposed of, gives effective consent, the embryo may be allowed to **succumb**.*

Consent for experimentation or diagnostic testing.

3.8 *A separate consent must be given to each **procedure, diagnostic test or experiment** that is subject to the **specific approval** of Council.*

Consent for the use of donor semen in special circumstances

3.9* *The semen of a **donor shall not be used in an artificial fertilisation procedure to which section 6 of the Artificial Conception Act does not apply unless the donor has specifically consented to the use of his semen in such a procedure.*

SECTION 4: INFORMATION

INFORMATION TO BE PROVIDED PRIOR TO CONSENT

*4.1 *Prior to the giving of effective consent to any artificial fertilisation procedure, the relevant licensee must ensure that participants 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 these 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), with its potential risks and side effects and longer term outcomes, for the participants and any child born;

. information about the keeping of registers for the purpose of monitoring and evaluating the procedures undertaken, including evaluation of their safety in both the short and the long term, and limitations to the research uses of these Registers being consented to, 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 results that identify any individual;

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; and

. information about the status of any innovative procedure being consented to, with its likelihood of success, risks etc for the participants and any child likely to be born.

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

*4.2 *Prior to consent to donation or use of donated human reproductive material, the relevant licensee 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 for these situations, and in particular, where semen donation is involved, as to the effect of sections 6 and 7 of the Artificial Conception Act and section 60B of the Family Law Act for any use under these circumstances.

. about the Donor Register with information about biological parentage, and drawing attention to the rights of access to non-identifying information that are given under the Reproductive Technology Act 1991 to children born or to the donors;

. there may be policy development towards legislation that would make available identifying information about their biological parentage to children of donors;

. about the medical, social (rearing) and secrecy implications in relation to donation and the rearing of donor children.

SECTION 5: COUNSELLING

THE PROVISION AND USE OF COUNSELLING SERVICES IN LICENSED PRACTICES.

Counselling in relation to IVF/GIFT

5.1 An IVF Practice licensee must provide access to counselling with a counsellor approved by the Reproductive Technology Council (an "approved counsellor") to all couples undergoing IVF/GIFT, to assist decision-making and provide support. This should be provided as part of normal routine without implying either that the person concerned is in any way deficient or abnormal, or that there is any pressure to accept and, within the limits specified below, this should be covered by the overall cost of the treatment, with no discount if not undertaken.

5.2 A couple could expect to be provided, within the overall cost of treatment, with one hour of counselling with an "approved counsellor" for each IVF/GIFT treatment cycle begun, and with one extra hour per couple that may be undertaken when the decision is being made to withdraw from further IVF/GIFT treatment.

5.3 For all IVF and GIFT couples this counselling should be provided routinely and strongly encouraged by the person responsible, but not mandatory, and each couple may choose, in consultation with the counsellor, how and when to take up their counselling quota.

5.4 The "approved counsellor" should be encouraged by the person responsible to offer a variety of group and individual counselling sessions, to offer support to other professionals employed within the licensed practice and, as appropriate, to coordinate with these other professionals to provide information sessions and the infra-structure for a patient support group.

5.5 The "approved counsellor" provided by the licensee to carry out counselling required by the Code must not be a person directly involved with the artificial fertilisation procedure being undertaken, but must be independent of that treatment.

COUNSELLING IN RELATION TO GAMETE DONATION

Anonymous donation

**5.6 Semen donors are not be expected to undergo mandatory counselling prior to anonymous donation, but the Storage licensee who collects and stores the semen must provide all semen donors with adequate information, in a form approved by Council, about all aspects and implications of donation, and the names of some "approved counsellors".*

5.7 Donors of eggs or embryos are not be expected to undergo mandatory counselling prior to anonymous donation, although all must be provided by the Practice licensee with adequate information, in a form approved by the Council, about all aspects and implications of their donation, and about the availability of an "approved counsellor" in the licensed practice. For those who are themselves being treated for infertility access to counselling by an "approved counsellor" should be provided by the Practice licensee as a routine part of their treatment and the donors should be strongly encouraged by the person responsible to undergo some counselling.

**5.8 All recipients of donated human reproductive material must be provided by the relevant Licensee or Exempt practitioner with comprehensive information about the medical, social and secrecy implications of rearing a child born after donation, in a form approved by Council, and should be strongly encouraged by the person responsible to undergo at least one session of counselling from an "approved counsellor".*

Known donors

*5.9 *Prior to an artificial fertilisation procedure where a donor is known to the recipients, the relevant licensee or Exempt practitioner must ensure that any donor or recipient involved, and their spouse or partner (if any), and/or guardian, undergoes at least one session of counselling with an "approved counsellor", and is provided with adequate information, in a form approved by Council, about all aspects and implications of the donation.*

SECTION 6: USE AND STORAGE OF GAMETES AND EMBRYOS.

Import and export of donated material.

**6.1* *A licensee may only accept from outside the State donated gametes or any embryo where donation of human reproductive material has been involved where all the information required by the Code of Practice or directions for the Donor Register is available, and may only allow the export from the State of donated gametes or of any embryo where inter-agency agreements ensure that all information as to outcome that is required by the Code of Practice or directions is to be available for the Registers.*

**6.2* *A licensee may apply to the Council for an exception to Rule 6.1, on compassionate grounds, on other terms.*

**6.3* *A licensee may accept from outside the State gametes or any embryo 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.*

6.4 *A licensee may not assist in the development of an embryo for export out of this State for a purpose other than would be allowed under the laws of this State.*

Maximum period of storage of gametes.

**6.5* *The maximum period for storage of gametes is 15 years, with a renewal of consent to be given every five years during this period. However, other than where the stored gametes are to be used for donation, an application may be made, in writing, to the Reproductive Technology Council, for an extension to this maximum period for storage.*

SECTION 7: ELIGIBILITY AND ASSESSMENT.

Minimum age for donation

**7.1* *A licensee may not accept gametes or any embryo for donation from a person aged under 18 years where these are to be used in an artificial fertilisation procedure.*

Who is to assess eligibility for treatment

7.2 *The Act specifies criteria that the licensee 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 person responsible must see to it 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 record reasons for this decision in his/her notes according to standard medical practice.*

7.3 *The role of the clinic-based counsellor must be clearly separated from the assessment process. In general if the counsellor has cause for concern as a result of information given to him/her in confidence, he/she should obtain the consent of the participant before discussing it 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 this and where, based on good professional practice, the counsellor should advise the medical practitioner of their concerns and suggest that a second opinion should be sought about matters that may affect the eligibility of the participant.*

SECTION 8: PRACTICE ISSUES.

PRACTICE IN RELATION TO DONATION

Limits to the number of offspring a donor may have

**8.1* *For each donor of gametes a licensee must limit to a maximum of five the number of known donee families, including families that may be interstate or overseas.*

Known donors

**8.2* *If where a donor is known to the recipient(s) and the donated gametes or embryo(s) to be used in the artificial fertilisation procedure are not to be stored and quarantined prior to use, the artificial fertilisation procedure must not take place earlier than 6-months after the initial agreement between the parties to the procedure, and the information to be given to the recipient(s) must include information about the fallibility of an HIV test under such circumstances.*

(See Direction 5.9 regarding counselling requirements under these circumstances)

OTHER PRACTICE ISSUES

Repeated ovarian stimulation

8.3 *There should be no further collection of eggs for the treatment of a particular couple if that couple have three or more stored embryo(s). 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.*

Avoidance of high multiple pregnancy

8.4 *The RTAC Code of Practice in relation to the avoidance of high multiple pregnancy is to be followed, with a maximum of three and in exceptional circumstances, four embryos or eggs to be transferred in any one cycle.*

Selective termination of pregnancy

8.5 *Selective termination of pregnancy should not be a part of routine practice.*

No posthumous use of gametes.

**8.6* *A licensee or Exempt practitioner must not knowingly use gametes in an artificial fertilisation procedure after the death of the gamete provider.*

SECTION 9: RESEARCH AND DIAGNOSTIC TESTING

PROCEDURES AND STANDARDS TO BE ADOPTED FOR THE APPROVAL OF ROUTINE LABORATORY AND CLINICAL PROCEDURES, ALL RESEARCH AND ALL DIAGNOSTIC TESTING OF EMBRYOS.

9.1 At the time of initial licensing:

the specific approval of Council must be obtained for any relevant, current-

research carried out or facilitated by a licensee;

diagnostic procedure involving an embryo; and

laboratory or clinical procedure that may be considered innovative according to the criteria set out in the guidelines; and

the general approval of Council must also be obtained for all clinical and laboratory procedures documented in a detailed manual and currently in place in the clinic where these procedures may be considered routine according to the criteria outlined in the guidelines .

9.2 For any subsequently proposed research, for any proposed diagnostic procedure involving an embryo or for any proposed clinical or laboratory procedure that may be considered innovative according to the criteria set out in the guidelines the specific approval of Council must be sought by application in the format outlined in the guidelines, and the research, diagnostic procedure or innovative laboratory or clinical procedure must not be implemented without this approval.

9.3 For any subsequent change or addition to the approved routine clinical or laboratory procedures the person responsible must update the procedure manual, notify the Executive Officer that a change has been made and be prepared to make this available to the Council on request. Prior to any approval of Council being given the lack of a request, or following a request the lack of any response from Council cannot be taken either as approval or an indication that approval is refused.

Council may then:

grant its general approval; or

request further information to assist consideration of its approval of 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 application be made for specific approval of the proposed change.

SPECIFIC RULES RELATING TO RESEARCH AND DIAGNOSTIC TESTING OF EMBRYOS

9.4 ***There is to be no development of any embryo, other than with a view to its future implantation in a particular woman, and the relevant consent should indicate this intention.***

9.5 *Where approval is sought from Council for any research or diagnostic procedure to be carried out upon or with an embryo, the application for approval must give 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 IDENTIFYING AND DEMOGRAPHIC INFORMATION

This must be sent in an electronic format.
This is required only ***once*** for each participant

Participant ID Code ☐☐☐☐☐☐☐☐

Sex ☐

Surname _____

Forename _____

Other forenames _____

Maiden name _____

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

Place of Birth WA ☐ Other State: specify _____

Other Country: specify _____

Occupation specify _____

Postcode of Residence ☐☐☐☐

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HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
IVF REGISTER

FORM 2 PARTICIPANT HISTORY

This form should be completed only once for each person (Male and Female) at the beginning of the first IVF treatment cycle (as defined by the HRT Act).

Licensee number ☐☐☐

Date this couple first started trying for a baby ☐☐ day ☐☐ month ☐☐ year

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

1. OBSTETRIC HISTORY

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)*

	Female	Husband/Partner
Gravida	☐☐	☐☐
Parity	☐☐	☐☐
Number of children of current relationship	☐☐	☐☐

2. PREVIOUS TREATMENT FOR INFERTILITY

Prior to this first IVF treatment cycle in this clinic has either person been involved (either directly or as a partner) in any of the following treatments: Please indicate with Y/N

Do both partners have the same history? (Y/N) ☐ *(if yes, complete for female only)*

	Female	Husband/Partner
Ovulation Induction	☐	☐
Timed Intercourse	☐	☐
AIH	☐	☐
DI	☐	☐
Chemical Stimulation of Sperm	☐	☐
Reversal of Sterilisation	☐	☐
Surgery (other than reversal)	☐	☐
IVF (as defined in the HRT Act, 1991)	☐	☐
If Yes, where?.....WA	☐	☐
Other State, specify	_____	_____
Other Country, specify	_____	_____
Other	☐	☐
specify	_____	_____

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3. CAUSE OF INFERTILITY

3.1 Female Factors *Tick all factors involved in infertility*

Participant ID Code Female ☐☐☐☐☐☐☐☐

None ☐ *(if none go to section 3.2)*

Unknown ☐

Egg/ovary ☐

Tubal occlusion Unilateral ☐ Bilateral ☐

Tubal factors other than occlusion ☐

Cervical factors ☐

Uterine factors ☐

Other ☐ specify _____

3.1.1 *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 _____			

3.2 Male Factors *Tick all factors involved in infertility*

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

None ☐

Unknown ☐

Azoospermia ☐

Oligospermia ☐

Asthenozoospermia ☐

Teratozoospermia ☐

Sexual and Ejaculatory dysfunction ☐

Other ☐ specify _____

3.2.1 *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 _____			

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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

Licensee number ☐☐☐

Oocyte retrieval code R☐☐☐☐☐☐☐☐☐ Date cycle commenced ☐☐ day ☐☐ month ☐☐ year

Participant ID code Female ☐☐☐☐☐☐☐☐

2. Medication During the Treatment Cycle leading to egg retrieval

	Drug	Total Dose	Number of Days
Down Regulation			
Stimulation			

General Anaesthetic Used ☐ Antibiotics ☐

3. Oocyte Retrieval

Cancelled ☐ Laparoscopy ☐ Trans vaginal Ultrasound ☐ Other ☐ specify _____

Number of eggs retrieved ☐☐ Number of eggs donated ☐☐

Number of eggs for experiments ☐☐ Recipient fertilisation code F☐☐☐☐☐☐☐☐☐☐

Number of eggs replaced by GIFT ☐☐ F☐☐☐☐☐☐☐☐☐☐

Number of eggs discarded ☐☐

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

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HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
IVF REGISTER

TREATMENT CYCLE INFORMATION

FORM 3B GIFT OR OOCYTE FERTILISATION

This form should be completed for each unique fertilisation, including gift, attempted. Please complete using text, numbers or ticks as appropriate.

1. Cycle Details

Licensee number ☐☐☐

Oocyte retrieval code R☐☐☐☐☐☐☐☐☐

Oocyte fertilisation code F☐☐☐☐☐☐☐☐☐

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

2. Sperm Preparation

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

or or

Donor sperm used ☐ ID code of donor ☐☐☐☐☐☐☐☐☐☐

surgery (eg Epididymal aspiration) ☐

washing only ☐

gradient ☐

swim up ☐

chemical stimulation ☐ specify _____

other ☐ specify _____

3. Fertilisation

GIFT transfer only (Y/N) ☐ Micro manipulation used (Y/N) ☐

Total number of eggs exposed to sperm invitro ☐☐

Total number of eggs fertilised ☐☐ Number of abnormally fertilised eggs ☐☐

Number of normally developing embryos ☐☐ Number of embryos failing to develop normally ☐☐

4. GIFT OUTCOME *(select one only) To be completed for GIFT only cycles*

No clinical pregnancy ☐ Termination of pregnancy ☐

Ectopic pregnancy ☐ Ongoing clinical pregnancy at 8 weeks ☐

Spontaneous abortion ☐ Other ☐ _____

4. Embryo Dispersal

Number of embryos for fresh transfer ☐☐ Number of embryos donated ☐☐

Number of embryos frozen ☐☐ Number of embryos discarded ☐☐

An embryo transfer form 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 and IVF ET procedure) or an FET. Please complete using text, numbers or ticks as appropriate.

1. Cycle Details

Licensee number ☐☐☐

Oocyte fertilisation code F ☐☐☐☐☐☐☐☐☐☐ F ☐☐☐☐☐☐☐☐

Embryo transfer code T ☐☐☐☐☐☐☐☐☐☐ Date cycle commenced ☐☐ day ☐☐ month ☐☐ year

Participant ID code Female ☐☐☐☐☐☐☐☐ Husband/Partner ☐☐☐☐☐☐☐☐

Date commenced trying for this baby ☐☐ day ☐☐ month ☐☐ year

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

Cancelled ☐ IVF+GIFT ☐ FET ☐

IVF ET ☐ ZIFT ☐ Other ☐ specify _____

3. Medication leading up to and following procedure

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

General Anaesthetic Used ☐ Antibiotics ☐

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

(tick either) Donor embryos used ☐ Own frozen embryos used ☐

Number of embryos thawed ☐ Number of thawed embryos unsuitable for implanting ☐

5. Embryo Transfer

Number of embryos transferred ☐

6. Final Outcome *(select only one)*

No clinical pregnancy ☐ Termination of pregnancy ☐

Ectopic pregnancy ☐ Ongoing clinical pregnancy at 8 weeks ☐

Spontaneous abortion ☐ Other ☐

Specify _____

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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 ☐ defacto ☐
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.

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HUMAN REPRODUCTIVE TECHNOLOGY ACT (1991)
DONOR REGISTER

FORM 5 TREATMENT INVOLVING DONOR SPERM

This form must be completed for each treatment involving donor sperm

Sperm storage licence number ☐☐☐

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

Donor code ☐☐☐☐☐☐☐☐☐☐

Recipient code ☐☐☐☐☐☐☐☐☐☐

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

Type of procedure

DI ☐

IVF ET ☐

GIFT ☐

ZIFT ☐

FET ☐

Have frozen embryos been stored Y(yes) or N(no) ☐

Outcome of procedure at 8 weeks:

no clinical pregnancy ☐

ectopic pregnancy ☐

spontaneous abortion ☐

termination of pregnancy ☐

ongoing clinical pregnancy at 8 weeks ☐

other, specify _____

outcome unknown ☐
reasons: _____

_____

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

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DONOR REGISTER

FORM 6 SPERM DONOR-IDENTIFYING INFORMATION

This information should be sent once a year in electronic format, for all sperm donors involved in an AF procedure whether or not a clinical pregnancy was achieved.

Licensee number ☐☐☐

Donor code ☐☐☐☐☐☐☐☐☐☐

Surname _____

Given name(s) _____

Date of Birth ☐☐ ☐☐ ☐☐
day month year

Postcode of residence ☐☐☐☐

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DONOR REGISTER

FORM 7 DI RECIPIENT IDENTIFING INFORMATION

This information is required for each recipient of donor sperm for DI where there is an ongoing clinical pregnancy at 8 weeks.

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

Licensee or Exemption number ☐☐☐

Recipient code ☐☐☐☐☐☐☐☐☐☐

Surname _____

Given name(s) _____

Maiden name (if applicable) _____

Date of Birth ☐☐ day ☐☐ month ☐☐ year

Postcode of residence ☐☐☐☐

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