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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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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* (the Act) 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 those who seek treatment. Research or treatment which involves the creation of embryos, their storage, and the storage of donated 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 (the Council), whose tasks include the provision of advice to Commissioner of Health on all matters relating to licensing, including the setting of suitable standards for licensees.

The Act was substantially amended in 2004 following the decision of the Council of Australian Governments for a nationally consistent approach to clinical practice associated with reproductive technology, and nationally consistent legislation prohibiting human cloning and other practices and regulating the use of embryos that are excess to the treatment needs of the persons for whom they were developed. These directions replace the directions given by the Commissioner of Health on 3 October 1997 and reflect amendments to the Act arising from the *Acts Amendment (Lesbian and Gay Law Reform) Act 2002*, the *Human Reproductive Technology Amendment Act 2004*, and the *Acts Amendment (Prohibition of Human Cloning and other Practices) Act 2004*.

It is recognised that 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 is able to monitor the procedures, especially for their long-term outcomes and safety with respect to any children born and to participants. The Reproductive Technology Registers record information about donors of reproductive material and children born as a result of this donation. Access to identifying and non-identifying information from the Registers 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 given by the Commissioner of Health on the advice of the Council and must be complied with by the licensees.

In framing these directions the Council has taken into account the following requirements of the 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 people who are unable to conceive children naturally or whose children may be affected by a genetic abnormality or a 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 these directions are welcome and may be addressed to—

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

INTERPRETATION

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

“**AI**” means artificial insemination;

“**AIH**” means artificial insemination using husband’s sperm;

“**ANZICA**” means the Australian and New Zealand Infertility Counsellors’ Association;

“**approved counsellor**” means a counsellor who has been assessed by the Council as meeting the requirements set out in Part 1 of Schedule 4;

“**authorised storage period**” in respect of embryos or eggs undergoing fertilisation means the shorter of—

(a) any period of time specified in the consent to store the embryo or egg;

(b) a period of 10 years or such longer period as approved by the Council under section 24(1a) of the Act;

“**Council**” means the Reproductive Technology Council;

“**DI**” means donor insemination;

“**egg**” means human egg;

“**embryo**” means human embryo;

“**exempt practitioner**” means a medical practitioner who is exempted under section 28 of the Act from the requirement to hold a licence to carry out artificial insemination procedures;

“**gametes**” means human gametes;

“**GIFT**” means Gamete Intra Fallopiian Transfer;

“**IVF**” means in vitro fertilisation;

“**NATA**” means the National Association of Testing Authorities;

“**NHMRC**” means the National Health and Medical Research Council;

“**NHMRC licence**” means a licence to use excess ART embryos granted by the National Health and Medical Research Council Licensing Committee in accordance with section 53ZB of the Act or section 21 of the *Research Involving Human Embryos Act 2002* (Cth) or under a corresponding law of a State or Territory;

“**required**” means required by the Act;

“**sperm**” means human sperm;

“**registers**” means the registers of identity required to be kept by the Commissioner of Health in accordance with section 45 of the Act;

“**RTAC**” means the Reproductive Technology Accreditation Committee of the Fertility Society of Australia;

“**Schedule**” means schedule to these directions;

“**the Act**” includes the *Human Reproductive Technology Act 1991* (as amended), regulations made under that Act and such directions as are published in the *Gazette* under that Act.

Note: Amendments made to the Act in 2004 have introduced a number of new terms and amended others. Attention is drawn to the following—

- “**eligible person**” is defined in section 24(2) of the Act and sets out the persons who are eligible to apply for an extension to the period of embryo storage. There is also a definition of eligible person in section 53ZL of the Act that relates only to persons who are eligible to apply for a review of a decision of the NHMRC Licensing Committee;
- “**licence supervisor**” is defined in section 3 of the Act and relates to a practice or storage licence issued under the Act. “Licence supervisor” replaces “person responsible” throughout the Act. This is a change in terminology only and the licence supervisor performs all the roles and functions previously performed by the person responsible;
- “**responsible person**” is defined in section 53T of the Act and relates only to persons who have decision-making responsibilities in relation to excess ART embryos.

In accordance with section 34 of the 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 Part 4 Division 3 of the Act.

In these Directions, a reference to a “licensee”, unless otherwise indicated, refers to the holder of a practice or storage licence, the licence supervisor, an exempt practitioner and the holder of an exemption under section 28A of the Act.

Directions marked with an * indicate directions that are of relevance to exempt practitioners.

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

PART 1: PERSONNEL, PREMISES AND MINIMUM STANDARDS OF PRACTICE**Part 4 of the Act.**

Note: It is a condition of each licence that the licensee is accredited to carry out reproductive technology by the RTAC and maintains such accreditation (section 33(2)(ea) of the Act). In addition to maintaining RTAC accreditation the following standards of practice are to be complied with.

1.1 Standards of practice, personnel and premises required for a practice licence—IVF

The licensee in relation to a practice licence that authorises IVF procedures must ensure that—

- (a) the minimum standards for practice, personnel and premises set by RTAC are met;
- (b) counselling by an approved counsellor is provided, in accordance with Part 5 of these directions;
- (c) laboratories are in compliance with relevant NATA standards; and
- (d) any other standards established under the Act are complied with.

1.2 Standards of practice, personnel and premises required for a practice licence—AI

The licensee 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 standards of good medical practice and any requirements established under the Act.

1.3 Standards of practice, personnel and premises for a storage licence—collection and storage

The licensee in relation to a storage licence authorising collection and storage of sperm for artificial fertilisation procedures involving donation, and/or the storage of eggs intended for use in an artificial fertilisation procedure, eggs undergoing fertilisation or embryos must ensure that—

- (a) the minimum standards for practice, personnel and premises set by RTAC are met;
- (b) laboratories are in compliance with relevant NATA standards;
- (c) a medical practitioner is employed to oversee screening of donors; and
- (d) any other standards established under the Act are complied with.

1.4 Standards of practice, personnel and premises for a storage licence —storage only

The licensee in relation to a storage licence which authorises the storage of donor sperm which is not collected on the premises, or sperm collected for artificial fertilisation procedures not involving donation, must ensure that—

- (a) the minimum standards for practice, equipment, staff and facilities comply with those required of good medical practice; and
- (b) any requirements established under the Act are complied with.

***1.5 Standards for an exemption for artificial insemination (exempt practitioner)**

Note: To be eligible under section 28 of the Act for an exemption from the licensing requirement for carrying out artificial insemination, a person must be a currently registered medical practitioner.

A medical practitioner who is an exempt practitioner must ensure that minimum standards for practice, equipment staff and facilities comply with those required of good medical practice and that any requirements established under the Act are complied with. An application for exemption must be made in the prescribed format and include evidence of registration as a medical practitioner, and a written undertaking by the medical practitioner to comply with the Code and directions.

1.6 Standards for an exemption for storage of excess ART embryos (holder of an exemption under section 28A of the Act)

The holder of an exemption from the requirement to hold a storage licence authorising the storage of an excess ART embryo under section 28A of the Act must ensure that—

- (a) as a minimum, standards for practice, equipment, staff and facilities comply with good laboratory practice;
- (b) any relevant conditions of the NHMRC licence are complied with; and
- (c) any requirements established under the Act are complied with.

1.7 Application for renewal of a licence

A licensee who is the holder of a storage or practice licence must apply for renewal of a licence no later than 3 months before its expiry.

1.8 Renewal in relation to an exemption under section 28A of the Act

The holder of an exemption under section 28A of the Act must apply for a new exemption in relation to each NHMRC licence held.

1.9 Notification in relation to an exemption under section 28A of the Act

The holder of an exemption under section 28A of the Act must notify the Commission of Health of any change to the NHMRC licence for which the excess ART embryos are being stored.

PART 2: RECORDS AND REPORTING**Part 4, Division 5 of the Act.*****2.1 Records to be kept by licensees**

A licensee must, in accordance with the Act and standards of good medical practice, maintain complete records of all keeping and use of gametes, eggs undergoing fertilisation and embryos with sufficient detail to enable compliance with reporting requirements under this Part.

***2.2 Period records to be retained**

A licensee must retain the original records indefinitely.

***2.3 Communication of information with a referring doctor**

A licensee 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.

***2.4 Informing doctor of confidentiality provisions**

Before a licensee provides information about the identity of a participant, donor or child born as the result of a procedure to a referring doctor, the licensee or exempt practitioner must ensure that the referring doctor is aware of the confidentiality provisions in section 49 of the Act.

***2.5 Reporting to a storage licensee who provides donated reproductive material**

A licensee who undertakes an artificial fertilisation procedure using donated gametes, embryos or eggs undergoing fertilisation that have been obtained from a storage licensee must provide to the storage licensee from whom the donated material was received the information as set out in Table 1.

TABLE 1

	Information to be provided to storage licensee
DI	
Exempt practitioner	Data provided in accordance with Form 5 (Schedule 1)
Practice licensee	Data provided in accordance with Part 2 of the Data Structure (Schedule 2)
IVF or GIFT	
Practice licensee	Data provided in accordance with Part 2 of the Data Structure (Schedule 2)

***2.6 Reporting to the Commissioner of Health on each artificial fertilisation procedure**

The licensee must provide to the Commissioner of Health for inclusion in the registers the information set out in Table 2 that is relevant to each artificial fertilisation procedure undertaken.

TABLE 2

	Treatment details and outcomes:	Participant ID:	DI Recipient ID Info:	Donor ID:	Donor Non ID Information:
Time information to be transferred	4 times per year as set out in the Data Structure in Schedule 2	Once per year on the request of the Register staff	On the request of the Register staff	Once per year on the Request of the Register staff	On the request of the Register staff
AIH					
Exempt practitioner	Nil	Nil	Nil	Nil	Nil
Practice licensee	Nil	Nil	Nil	Nil	Nil
DI					
Exempt practitioner	N/A	N/A	Form 7 (Schedule 1)	Nil	Nil
Practice licensee	Information in Part 2 of the Data Structure in Schedule 2	N/A	Information in Part 1 of the Data Structure in Schedule 2	N/A	N/A
IVF or GIFT					
Practice licensee no donation involved	Information in Part 2 of the Data Structure in Schedule 2	Information in Part 1 of the Data Structure in Schedule 2	N/A	N/A	N/A
Practice licensee with donation	Information in Part 2 of the Data Structure in Schedule 2	Information in Part 1 of the Data Structure in Schedule 2	N/A		

	Treatment details and outcomes:	Participant ID:	DI Recipient ID Info:	Donor ID:	Donor Non ID Information:
Storage licensee					
Donor semen provided to exempt practitioner for DI	Information in Part 2 of the Data Structure in Schedule 2	N/A	Nil	Information in Part 1 of the Data Structure in Schedule 2	Information in Form 4 in Schedule 1
Donor semen provided to practice licensee	Nil	Nil	Nil	Information in Part 1 of the Data Structure in Schedule 2	Information in Form 4 in Schedule 1

2.7 Manner of transfer of information for the registers

A practice licensee or storage licensee must provide all treatment details and named identifying information to the Commissioner of Health for inclusion in the registers in accordance with the requirements set out in the Data Structure in Schedule 2.

*2.8 Exempt practitioners may provide hard copies

An exempt practitioner may provide the required information to the Commissioner of Health for inclusion in the registers in hard copy, using Forms 4-7 from Schedule 1 to these directions, as applicable.

2.9 Timing of transfer of information for the registers

A licensee must provide the required information about treatment details to the Commissioner of Health for inclusion in the registers in accordance with the dates set out in the Data Structure in Schedule 2 and Table 2.

*2.10 Restriction on provision of donate semen to medical practitioners

A storage licensee must not provide semen to a medical practitioner for DI unless that practitioner is currently exempt under the Act or where there is Council approval for the export under direction 6.6.

*2.11 Restriction on provision of reproductive material to practice licensees, storage licensees or exempt practitioners

A storage licensee must not provide donated human reproductive material to any practice licensee, storage licensee, exempt practitioner or any other person under their supervision, unless that person has provided the information set out in direction 2.5 in respect of donated reproductive material previously provided by the storage licensee and has done so as soon as practicable after that material was provided.

*2.12 Transfer of responsibility to report to the Commissioner of Health

A licensee, including the holder of an exemption under section 28A of the Act, who accepts gametes or an embryo from another person for storage, is responsible for the provision of any report required in respect of those gametes or that embryo.

*2.13 Exceptions to the requirement to report donor identity

A licensee is not required to supply to the Commissioner of Health for inclusion in the registers information that includes the identity of the donor of any reproductive material used—

- (a) in respect of human embryos already in store at the time the Act came into operation, if the donor did not agree to the disclosure of his or her name to the registers at the time the gametes were provided, and—
 - (i) the licence supervisor 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
 - (ii) the donor has been asked to agree to the registration of his or her identity and has refused;
 and
- (b) in respect of donor gametes in store at the time the Act came into operation, if 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
 - (i) the licence supervisor 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
 - (ii) the donor has been asked to agree to the registration of his or her identity and has refused.

*2.14 Reasons for non-inclusion of donor identity

A licensee, including an exempt practitioner, must at the time of registration of information, provide the reasons for non-inclusion of identity of the donor.

2.15 Reporting on excess ART embryos donated for research

A storage licensee must provide to the Commissioner of Health for inclusion in the registers, information set out in Part 3 of the Data Structure in Schedule 2 that is relevant to each excess ART embryo that has been donated for research.

2.16 Copies of reports to NHMRC Licensing Committee to be provided to Council

A licensee, including the holder of an exemption under section 28A, must provide the Council with a copy of any report provided to the NHMRC Licensing Committee in connection with an NHMRC licence held by the licensee.

2.17 Timing of transfer of information to the Register

A storage licensee must provide the required information about excess ART embryos to the Commissioner of Health for inclusion in the registers in accordance with the dates set out in the Data Structure in Schedule 2.

***2.18 Annual reporting**

The licensee must submit an annual report including the information set out in Table 3 to the Commissioner of Health by 31 July each year relating to the previous financial year for each category of licence held.

TABLE 3

	Information to be provided
Exempt Practitioner	Information about intra-uterine insemination procedures carried out (including Nil return) in accordance with Part 1 Schedule 3
Practice licensee	<ul style="list-style-type: none"> • Information in accordance with Part 2 Schedule 3 • Information about counselling provided in accordance with Part 5 Schedule 3
Storage licensee: about donated semen	<ul style="list-style-type: none"> • Information in accordance with Part 3 Schedule 3 • Information about counselling provided in accordance with Part 5 Schedule 3
Storage licensee: about embryos	Information in accordance with Part 4 Schedule 3

2.19 Notification of change in circumstances or details of licensee

A practice or storage licensee must notify the Commissioner of Health in accordance with the method of required notification in direction 2.21 if any of the following events occur—

2.19.1 Insolvency Events

- (a) if the licensee is a corporation, it becomes insolvent (as that term is defined in section 9 of the *Corporations Act 2001* (Cth));
- (b) 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;
- (c) if the licensee is a natural person, he or she becomes insolvent (as that term is defined in section 9 of the *Corporations Act 2001* (Cth));
- (d) if the licensee is a firm—
 - (i) an event specified in paragraph 2.19.1 (a), (b), or (c) occurs with respect to any member of the firm or the firm;
 - (ii) any action is commenced pursuant to section 46 of the *Partnership Act 1895* or otherwise to dissolve the firm;

2.19.2 Change in Constitution of Board/Firm/Trust

- (e) if the licensee is a body corporate, there is any change proposed or any change occurs in the constitution of the board of directors;
- (f) if the licensee is a firm there is any change proposed or any change occurs in the membership of the firm;
- (g) if the licensee is a trustee of—
 - (i) a unit trust, there is any change proposed or any change occurs in—
 - (I) the number of units on issue in the trust;
 - (II) the rights that attach to any units on issue; or
 - (III) the holders of the units on issues;
 - (ii) a discretionary trust, there is any change proposed or any change occurs in—
 - (I) the class of beneficiaries who may benefit under that trust;
 - (II) the appointor, controller or guardian of that trust;

2.19.3 Change of Control

- (h) 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 Act 2001* (Cth)) is made or announced with respect to all or any of the shares on issue in the licensee;

2.19.4 Investigation

- (i) if an investigation is commenced pursuant to section 13 of the *Australian Securities and Investment Commission Act 2001* (Cth) or otherwise to investigate the affairs or any of the affairs of the licensee;

2.19.5 Change in Management Personnel, or Premises

- (j) if any change is proposed or any change occurs in management personnel or premises, at the licensed premises;
- (k) Without limiting the generality of this requirement, changes to be notified include any significant periods of absence of the licence supervisor from the licensed premises or a change of medical director;

2.19.6 Litigation or Arbitration Proceedings

- (l) if —
 - (i) the licensee;
 - (ii) where the licensee is a body corporate—any director, secretary or executive officer of the licensee; or
 - (iii) if the licensee is a firm—any of its members,
is prosecuted for an alleged breach of any Commonwealth or State legislation;
- (m) if any judgement or award is entered—
 - (i) against the licensee in an amount exceeding \$50 000;
 - (ii) where the licensee is a body corporate—against any director, secretary or executive officer of the licensee in an amount exceeding \$10 000; or
 - (iii) if the licensee is a firm—against any of its members in an amount exceeding \$10 000;

2.19.7 Change in Business

- (n) if the licensee proposes to cease or ceases to carry on business either generally or at the premises described in the licence;

2.19.8 Change in Circumstances

- (o) if any change occurs in the circumstances or details that the licensee was required to provide in the licensee's application for a licence or exemption.

2.20 Required notification of changes to patient information and consent forms

The licensee must notify the Council of any change to a relevant 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.

2.21 Method of required notification

Notifications called for by directions 2.19 and 9.2 must—

- (a) be in writing and must 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 provided;

- (b) be sent to the Commissioner of Health within 48 hours of the occurrence of the relevant event; and
- (c) contain sufficient information to enable the Commissioner of Health to assess whether the matters set out in sections 29(4), 29(5) and 29(6), and section 30(1) of the Act continue to be satisfied.

2.22 Further particulars

If the Commissioner of Health requests the licensee to—

- (a) provide further particulars concerning the occurrence of any notified event; or
- (b) advise in writing, if any of the events specified in directions 2.19.1-8 have occurred,

the licensee must, within any time limit specified, provide the Commissioner of Health with a written response containing such further particulars as requested.

PART 3: CONSENT**Part 3, Division 2 of the Act.**

Note: Under section 33(2)(e) of the Act, it is a condition of all licences and exemptions that consent requirements set out in section 22(1) of the Act are complied with.

3.1 Consent for keeping any gametes to be renewed every 5 years

Subject to directions 6.8 and 6.9, the licensee must ensure that consent to store gametes is renewed every 5 years.

***3.2 Consent to artificial fertilisation procedure**

Any person to whom the licence applies, including an exempt practitioner, who proposes to carry out or to direct the carrying out of an artificial fertilisation procedure must—

- (a) at the time of or immediately prior to an IVF procedure, ensure that effective consent to the procedure and to the use of the gametes or embryos (including if relevant consent to the use of donated gametes or embryos), is given by the recipient and the recipient's spouse or de facto partner (if any);
- (b) at the time of or immediately prior to an AI procedure, ensure that effective consent to the procedure and to the use of the gametes (including if relevant consent to the use of donated gametes), is given by the recipient and the recipient's spouse or de facto partner (if any); and
- (c) ensure that any other person required under the Act to give effective consent has done so.

***3.3 Consent to use of donated gametes**

Any person to whom the licence applies, including an exempt practitioner, must ensure that, prior to the donation of gametes for their use in an artificial fertilisation procedure, effective consent is given by the gamete provider and the gamete provider's current spouse or de facto partner (if any) to the donation and use of the gametes.

3.4 Consent to use of embryo or egg undergoing fertilisation

Prior to the donation of an embryo or egg undergoing fertilisation for use in an artificial fertilisation procedure, any person to whom the licence applies must ensure that—

- (a) effective consent to the donation and use is given by the person(s) for whom the embryo or egg was developed; and
- (b) any person who donated gametes used to develop the embryo or egg, and the spouse or defacto partner of the gamete provider (if any) gave effective consent to the use at the time the donation was made.

3.5 Donors and recipients of gametes, embryos and eggs undergoing fertilisation to be aware of *Artificial Conception Act 1985

Any person to whom the licence applies, including an exempt practitioner, who proposes to use donated gametes, embryos or eggs undergoing fertilisation in an artificial fertilisation procedure must ensure that the donor(s) and recipient(s) are aware of the impact of the *Artificial Conception Act 1985* on the legal parentage of a child born as a result of the procedure.

3.6 Consent to allow an embryo to succumb

The licensee must ensure that any consent to storage of an embryo or egg undergoing fertilisation includes consent to remove the embryo or egg from storage and allow it to succumb at the end of any authorised storage period.

3.7 Consent for innovative procedures, research or diagnostic testing

The licensee must ensure that participants(s) give a separate consent to each innovative procedure, diagnostic procedure or any research that is subject to the approval of Council.

3.8 Consent for the use of excess ART embryos

The license supervisor must ensure that no embryo is provided for use in connection with an NHMRC licence unless—

- (a) the embryo has been declared to be an excess ART embryo by the woman for whom it was created and her spouse or de facto partner (if any); and
- (b) proper consent to the use of the embryo for the purposes authorised under the NHMRC licence has been given by each responsible person.

3.9 Donors of excess ART embryos for research to be informed that further, specific consent may be required

The licensee must ensure that donors of excess ART embryos for research are informed that further specific consent for use of the embryo in a particular project may be required in the future and that they may refuse to give such consent.

3.10 Donors of excess ART embryos for research to be informed of eligibility to apply for an extension of storage period

The licensee must ensure that donors of excess ART embryos for use in providing treatment to another person or couple are informed that they may be eligible to apply for an extension of the storage period of an embryo that has not yet been used. The donors should be given the option of indicating whether they want to be contacted in accordance with the provisions in section 24(3) of the Act if the embryo is still in storage.

PART 4: INFORMATION**Part 3, Division 2 of the Act, section 22 in particular.*****4.1 Information to be provided prior to consent**

Prior to participant/s giving effective consent to any artificial fertilisation procedure, the licensee must ensure that they are given oral explanations supported by relevant written material in a form approved by Council, including—

- (a) information about the effects of the consents given, and the ability to place conditions on, and to vary or withdraw consents;
- (b) 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);
- (c) the potential risks, side effects, longer term outcomes, and limitations to current knowledge, for the participants and any child born;
- (d) advice about the requirements under the Act that information in relation to each artificial fertilisation procedure is to be provided to registers kept by the Commissioner of Health and that information in the registers may be used, in accordance with the requirements of the Act and Department of Health confidentiality procedures, for the purposes of—
 - (i) administration of the Act;
 - (ii) monitoring and evaluating the procedures undertaken, including the evaluation of the safety of those procedures for participants and children born as a result of the procedure, in both the short and the long term; or
 - (iii) bona fide medical or public health research into reproductive technology; without the participant being contacted for consent (except in limited circumstances);
- (e) 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;
- (f) information about counselling, including—
 - (i) counselling requirements and entitlements under the Act;
 - (ii) the availability of counselling through the licensed practice;
 - (iii) advice that a counselling service is provided to assist decision-making and provide emotional and therapeutic support, such as grief/loss counselling; and
 - (iv) encouraging counselling from an approved counsellor;
- (g) information that the use of gametes in an artificial fertilisation procedure where the provider of the gametes is known to be dead is not permitted;
- (h) information about the *Privacy Act 1988* (Cth) and the clinic's privacy policy.

***4.2 Additional information to be given in relation to the use of donated reproductive material**

The licensee must ensure that, prior to consent being given for the donation or use of donated human reproductive material in an artificial fertilisation procedure, all donors and recipients are given oral explanations, supported by relevant written information in a form approved by Council, including information about—

- (a) the effect of the *Artificial Conception Act 1985*;
- (b) information that is included on the registers in relation to the donated material, its use and the biological parentage of any child born as a result of the use;
- (c) rights of donors, participants and children born as a result of the donation to access identifying and non-identifying information in accordance with the Act;
- (d) the medical and social implications in relation to donation and for children born as a result of the donation;
- (e) the need to refrain from unprotected sexual intercourse during the course of treatment to avoid confusion about the biological parentage of any child born;
- (f) limitations on the storage periods permitted for the reproductive material and requirements of the Act in relation to seeking extension of the storage period.

4.3 Information to be given in relation to the use of donated embryos for a use requiring an NHMRC licence

The licensee must ensure that, prior to consent being given, persons wishing to donate excess ART embryos for a use which requires an NHMRC licence are given oral explanations, supported by relevant written information in a form approved by Council, including information about—

- (a) procedures under Part 4B of the Act and the *Research Involving Human Embryos Act 2002* (Cth) for obtaining consent to the use of an excess ART embryo for a specific NHMRC licence, including advice that consent for a specific use may be requested at some future date and that the person has the right to refuse to give that consent;
- (b) rights to place conditions on the uses to which the embryo may be put;
- (c) rights to withdraw consent prior to use of the embryos; and
- (d) limitations on the storage period for embryos, including advice that the licensee may apply for approval to extend the storage of an embryo unless the person who is donating the embryo has advised that they wish the embryo to be removed from storage at a specified time.

PART 5: ASSISTANCE WITH DECISION MAKING AND COUNSELLING**Section 22 of the Act.**

Note: Section 22(7) of the Act requires that before a licensee gives effect to a consent for the purposes of the Act each participant must have been given the opportunity to receive proper counselling about the implications of the proposed procedure. The directions in this Part set out the minimum requirements to be met by a licensee in relation to counselling.

5.1 Persons undergoing an IVF procedure to have access to an approved counsellor

The licensee must ensure that all persons undergoing an IVF procedure have access to an approved counsellor.

5.2 Approved counsellor not to be a staff member directly involved with the artificial fertilisation procedure

The licensee must ensure that the approved counsellor is an integral member of the clinic team, but is not a staff member directly involved with the artificial fertilisation procedure being undertaken, and is not involved in assessment of the suitability of a participant to undergo treatment.

5.3 Cost of treatment to include time with approved counsellor

The licensee must ensure that the overall cost of treatment includes the cost of at least one consultation with an approved counsellor for each IVF cycle begun. The licensee must not provide a discount to a participant on the basis that the participant chooses not to use the counselling included in the overall cost of treatment.

5.4 Cost of counselling to be transportable

The licensee must ensure that the cost of counselling included in the overall cost of treatment is transportable, by prior arrangement between the participant/s and the licensee, towards the costs of a participant's attendance at an approved counsellor outside the licensed practice.

5.5 IVF participants must be provided with information as to counselling entitlements

The licensee must ensure that participant/s proposing to undergo an IVF procedure is/are provided with information about their entitlements to counselling and the options that available in relation to how and when and if to take up the entitlement and that they are strongly encouraged to undertake such counselling.

***5.6 Information about counselling to be provided to donors of semen where recipient is unknown to the donor**

The licensee must ensure that where the recipient is unknown to the donor, the semen donors, are provided with adequate information, in a form approved by Council, that—

- (a) encourages the donor to seek assistance with decision making and counselling in preparation for donation;
- (b) provides information about the availability of approved counsellors to assist with decision-making, including a list of approved counsellors; and
- (c) provides information about the possible impacts of becoming a donor, including medical, social, secrecy and disclosure implications of donation.

5.7 Information about counselling to be provided to donors of eggs, embryos or eggs undergoing fertilisation where recipient is unknown to the donor

The licensee must ensure that where the recipient is unknown to the donor, the donors of eggs, embryos or eggs undergoing fertilisation, are provided with adequate information, in a form approved by the Council, that—

- (a) strongly encourages the donor to seek assistance with decision making and counselling from an approved counsellor and provides a list of approved counsellors;
- (b) sets out the availability of and entitlement to, counselling through the licensed practice; and
- (c) provides information about the possible impacts of becoming a donor, including medical, social, secrecy and disclosure implications of donation.

***5.8 Psycho-social preparation required where recipient is known to the donor**

Prior to any artificial fertilisation procedure involving donated reproductive material where a potential donor is known to the recipients, the licensee must ensure that the donor and recipient involved, and the spouse or de facto partner of the donor and recipient (if any), have undertaken psycho-social counselling as set out in Part 2 of Schedule 4 or such other psycho-social preparation as has been approved by the Council.

5.9 Counselling prior to provision of information about the identity of a donor, participants or child born as a result of any artificial fertilisation procedure

Note: Information which discloses, or may disclose the identity of a donor, participant or child born as a result of an artificial fertilisation procedure may only be provided in accordance with section 49 of the Act.

The licensee must ensure that prior to counselling required under section 49 of the Act being undertaken, approval of the Commissioner of Health has been obtained.

PART 6: TRANSFER AND STORAGE OF GAMETES AND EMBRYOS**Sections 22-26 of the Act.*****6.1 Import of reproductive material generally**

Note: In addition to requirements in relation to import of donated material under the Act, the *Customs (Prohibited Imports) Regulations 1956* (Cth) apply to the import of embryos to Australia.

A person to whom the licence applies may only accept gametes, embryos or eggs undergoing fertilisation from outside the State if—

- (a) the gametes are to be used in an artificial fertilisation procedure;
- (b) the embryo or egg undergoing fertilisation is to be used in an artificial fertilisation procedure;
- (c) the material is to be used in a research project that has been approved by the Council; or
- (d) the embryo is an excess ART embryo that is to be used under an NHMRC licence.

***6.2 Import of donated reproductive material**

Except as approved under direction 6.3, a person to whom the licence applies must not, without the approval of the Council, accept from outside the State for use in an artificial fertilisation procedure, gametes, embryos or eggs undergoing fertilisation where donation of human reproductive material has been involved, if the information that would be required under the Act for the registers, had the donated human reproductive material been collected in this State, is not available to him/her.

***6.3 Council may approve import without information for registers**

The Council may, on compassionate grounds, approve the import of donated gametes, embryos or eggs undergoing fertilisation where the required information is not available.

6.4 Export of embryos for prohibited uses

Note: In addition to requirements in relation to export of donated material under the Act, the *Customs (Prohibited Exports) Regulations 1958* (Cth) apply to the export of embryos from Australia.

A person to whom the licence applies must not permit or facilitate the export from the State of an embryo for a use that would not be permitted under the Act.

***6.5 Export of donated gametes, embryos or eggs undergoing fertilisation for use in an artificial fertilisation procedure**

A person to whom the licence applies must not, without the approval of the Council, permit or facilitate the export from the State for use in an artificial fertilisation procedure, gametes, embryos or eggs undergoing fertilisation where donation of human reproductive material has been involved.

***6.6 Council may approve export of donated gametes, embryos or eggs undergoing fertilisation for use in an artificial fertilisation procedure**

The Council may approve the export for use in an artificial fertilisation procedure of donated gametes, embryos or eggs undergoing fertilisation to an approved person who has given a written undertaking using Form 10 in Schedule 1, to provide the licensee with information that would be required for the registers, had the donated material been used within this State. Where the undertaking to provide information is not completed within a reasonable time, the approval of the Council to export may be withdrawn and the failure to comply with the undertaking may be taken into consideration in any future application for approval to export to that person.

6.7 Transfer of excess ART embryos

The licensee must ensure that if an excess ART embryo is transferred to another person, that person—

- (a) is the holder of a storage licence;
- (b) has been granted an exemption under section 28A of the Act; or
- (c) is the holder of an NHMRC licence that authorises the use of the excess ART embryo.

***6.8 Maximum period of storage of gametes**

Note: The Act does not regulate the removal and storage of ovarian or testicular tissue. However, subsequent storage or use of gametes taken from gonadal tissue for research or in an artificial fertilisation procedure is regulated by the Act. Women or men for whom gonadal tissue is being stored should be informed that any future use of the tissue in an artificial fertilisation procedure will require approval by the Council. In considering whether to grant such approval the Council must consider knowledge available at the time about the safety and effectiveness of the procedures and outcomes, both for the woman and any potential offspring, and such approval cannot be assumed.

The licensee must ensure that gametes are not, without the approval of the Council, stored for longer than 15 years.

***6.9 Council may approve extension of storage period for gametes**

The Council may approve an extension of the storage period for gametes, on the application of the licensee or the gamete provider, if the stored gametes are to be used in treatment of the gamete provider or for research.

6.10 Records of period of storage of embryos and eggs undergoing fertilisation

The licensee must ensure that—

- (a) records are maintained to accurately reflect the expiry date of the authorised storage period for each embryo and egg undergoing fertilisation; and
- (b) a system is in place to identify embryos or eggs undergoing fertilisation that are nearing the expiry of the authorised storage period and to notify persons on whose behalf those embryos or eggs are being stored.

Note: The licensee has a potential liability to the persons for whom the embryo or egg undergoing fertilisation is stored if the notification requirements in section 24(3) of the Act have not been complied with before the embryo is removed from storage. To avoid such liability it is in the interests of the licensee to ensure that the steps they have taken to notify the persons of the expiry of the storage period are reasonable. Such steps may include writing to the person at the last known address, writing to the person at an address obtained from an electoral roll search, or telephoning or contacting the person's general practitioner or any other suitable third party.

6.11 Embryo or egg undergoing fertilisation must be allowed to succumb

The licensee must ensure that at the expiry of the authorised storage period for an embryo or egg undergoing fertilisation, the embryo or egg is removed from storage and allowed to succumb.

6.12 Extension of storage period for embryos and eggs undergoing fertilisation for use in an artificial fertilisation procedure

Note: The licensee cannot apply for an extension of the storage period for an embryo or egg undergoing fertilisation that is to be used in an artificial fertilisation procedure.

The licensee must ensure that—

- (a) information is provided to persons on whose behalf an embryo or egg undergoing fertilisation is being stored for use in an artificial fertilisation procedure, about the possibility that the person may apply to the Council, using Form 8 in Schedule 1, for an extension of the storage period, and that such an application must be received by the Council at least one month before the Council meeting that precedes the expiry of the storage period;
- (b) if required, assistance with completion of Form 8 is provided to a person who wishes to seek an extension to the authorised storage period.

6.13 Extension of storage period for excess ART embryos donated for research

The licensee or the person(s) for whom the embryo was developed may apply to the Council using Form 9 in Schedule 1 for approval to extend the storage of an excess ART embryos that have been donated for a use requiring an NHMRC licence.

6.14 Time for applications for approval to extend storage period of excess ART embryo

The licensee must ensure that an application for approval to extend the storage period of an excess ART embryo that has been donated for research is received by the Council at least one month prior to the meeting of the Council that precedes the expiry of the storage period.

PART 7: ELIGIBILITY AND ASSESSMENT**Divisions 2 and 3 of Part 3 of the Act.*****7.1 Minimum age for donation**

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

***7.2 Donor not to have been coerced**

The licensee must ensure that each donor of gametes, embryos or eggs undergoing fertilisation where the recipient is known to the donor is carefully assessed to ensure that the donor has not been coerced into making the donation.

***7.3 Sperm from a woman's male relative not to be used in artificial fertilisation of the woman's ova**

The licensee must ensure that if a woman's ova are to be used in an artificial fertilisation procedure, sperm from the woman's grandfather, father, son, grandson, brother or half-brother is not used in the procedure.

***7.4 Ova from a man's female relative not to be fertilised with the man's sperm**

The licensee must ensure that if a man's sperm is to be used in an artificial fertilisation procedure, ova of the man's grandmother, mother, daughter, grand-daughter, sister or half-sister are not used in the procedure.

7.5 Medical practitioner to maintain a record of reasons for decision relating to eligibility for IVF treatment

Note: Section 23 of the Act sets out the requirements to be met for eligibility for an in-vitro fertilisation procedure.

The licensee must ensure that the medical practitioner treating the patient maintains a record of the reasons for a decision about eligibility for IVF treatment in accordance with standards of good medical practice and the requirements of the Act.

7.6 Role of counsellor to be separate from assessment process

The licensee must ensure that the role of the counsellor is clearly separated from the assessment process unless—

- (a) the participant consents to the counsellor discussing any matter with the medical practitioner treating the patient; or
- (b) the counsellor, based on standards of good professional practice, has serious concerns about the welfare of a participant, or of a child who may be born as a result of a procedure.

7.7 IVF treatment to avoid likely transmission of an infectious disease

The licensee must ensure that an IVF procedure directed at reducing the risk of transmission of an infectious disease, such as AIDS or hepatitis, is not undertaken without the prior approval of the Council.

PART 8: SPECIFIC CLINICAL PRACTICE ISSUES**Part 3 of the Act.*****8.1 Limits to the recipient families using gametes of a donor**

The licensee must ensure that for each donor of gametes there are no more than 5 recipient families known to the licensee, including families that may be outside Western Australia, unless the Council has given approval.

***8.2 Council may approve a use that may result in more than 5 recipient families in exceptional circumstances**

The Council may approve the use of a donated embryo or egg undergoing fertilisation created using donated gametes in an artificial fertilisation procedure that may result in more than 5 recipient families in exceptional circumstances.

***8.3 Restriction on use of donated reproductive material**

The licensee must ensure that donated sperm, eggs, eggs undergoing fertilisation or embryos are not used in an artificial fertilisation procedure unless RTAC guidelines in relation to screening and quarantine have been complied with.

8.4 Restriction on use of fresh donated eggs

The licensee must ensure that fresh donated eggs are not to be used in an artificial fertilisation procedure, including the creation of an embryo for fresh transfer, where the recipient is known to the donor, unless—

- (a) the recipient(s) has been given information about the fallibility of an HIV test under such circumstances; and
- (b) a period of at least 6 months has elapsed between the donor and recipient completing psycho-social preparation as required in accordance with Direction 5.8.

***8.5 Restrictions on use of reproductive material donated prior to 1 December 2004**

A licensee must ensure that reproductive material donated before the commencement date of the *Human Reproductive Technology Amendment Act 2004* (1 December 2004) is not used in an artificial fertilisation procedure unless—

- (a) each donor has been given information about the changes to the Act in relation to the rights of donor offspring who has reached 16 years of age to be given identifying information about the donor, and the donor has given consent after 1 December 2004 to the use of the donation in an artificial fertilisation procedure; or
- (b) donated gametes are stored for a woman who wishes to have a full sibling for an existing donor child, and—
 - (i) the licence supervisor has not been able to contact the donor(s) to obtain his or her consent to the provision of identifying information to a future donor offspring who has reached 16 years of age despite reasonable efforts to do so; or
 - (ii) the donor(s) has been asked to consent to the provision of identifying information to a future donor offspring who has reached 16 years of age and has refused;

or

- (c) an embryo was created before 1 December 2004, and—
 - (i) the licence supervisor has not been able to contact each person who provided gametes used in the creation of the embryo to obtain his or her consent to the provision of identifying information to a future donor offspring who has reached 16 years of age despite reasonable efforts to do so; or
 - (ii) each person who provided gametes used in the creation of the embryo donor(s) has been asked to consent to the provision of identifying information to a future donor offspring who has reached 16 years of age and has refused;

or

- (d) the conditions set out in section 49(2e)(b)(ii) of the Act have been complied with in respect of the donation.

***8.6 No deliberate confusion of biological parentage**

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, embryos or eggs undergoing fertilisation to be mixed in the procedure in such a manner as may create confusion as to the biological parentage of any child born.

8.7 Restrictions on collection of eggs

Any person to whom the licence applies must not, without the approval of the Council, allow collection of eggs where they are to be used in the development of embryos or eggs undergoing fertilisation for the treatment of a participant who has, at that time, the right to make decisions about 3 or more stored embryos of the same biological parentage. However, if there are only one or 2 embryos of the same biological parentage in storage for that participant, a further egg collection may be carried out.

8.8 Council may approve collection of eggs despite direction 8.7 in exceptional circumstances

Council may approve the collection of eggs from a participant who has 3 or more embryos or eggs undergoing fertilisation in storage in exceptional circumstances.

***8.9 No posthumous use of gametes**

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.

PART 9: APPROVAL OF LABORATORY AND CLINICAL PROCEDURES**Section 20 of the Act.****9.1 Requirement to maintain a protocol manual**

The licensee (other than an exempt practitioner) must ensure that a protocol manual complying with the requirements set out in Part 1 of Schedule 5 is kept and maintained.

9.2 Approval of routine laboratory and clinical procedures

The licensee must ensure that all routine procedures to be followed are set out in a detailed protocol manual for which the approval of Council is obtained. Routine procedures are procedures that meet the criteria outlined in Part 2 of Schedule 5.

9.3 Changes to approved routines or procedures

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

- (a) the manual must be updated, and dated and approved by the licensee, at or before the time the change is introduced;
- (b) the manual must be provided to the Council at any time on request;
- (c) 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.]
- (d) the Council may—
 - (i) grant its general approval;
 - (ii) 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
 - (iii) 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;
- (e) approval of the changes is not to be inferred from failure of the Council to respond;
- (f) where there is any doubt as to whether or not the proposed change would be considered routine or innovative, the licensee should ensure that the matter is raised with the Council prior to introduction of the change, by notification in accordance with Direction 2.21.

9.4 Approval for innovative procedures

The licensee must ensure that each clinical or laboratory procedure that may be considered innovative has the specific approval of the Council before being undertaken and is not carried out without such approval. A procedure is considered innovative if it does not meet the criteria for routine procedures in Part 2 of Schedule 5.

9.5 Applications for approval for innovative procedure

The licensee may apply to the Council using Form 1 in Schedule 1 for approval for an innovative clinical or laboratory procedure.

9.6 Approval for research

The licensee must ensure that each research project, other than a research project that requires an NHMRC licence, has the specific approval of the Council before being undertaken and is not carried out without such approval.

9.7 Applications for approval for research

The licensee may apply to the Council using Form 2 in Schedule 1 for approval for a research project other than a research project that requires an NHMRC licence.

9.8 Application for embryo research to include evidence of matters referred to in section 14(2a) of the Act

The licensee must ensure that an application to the Council for the approval of any research to be carried out upon or with an embryo includes evidence of those matters in section 14(2a) of the Act about which the Council must be satisfied before granting approval.

9.9 Approval of diagnostic procedures involving embryos

The licensee must ensure that each diagnostic procedure involving an embryo or egg undergoing fertilisation has been approved by the Council before the procedure is undertaken.

9.10 Applications for approval of diagnostic procedures involving embryos

The licensee may apply for approval to undertake diagnostic procedure involving an embryo in a form approved by the Council.

9.11 Application for approval of diagnostic procedures involving embryos to include evidence of matters referred to in section 14(2b) of the Act

The licensee must ensure that an application for approval of a diagnostic procedure includes evidence of those matters in section 14(2b) of the Act about which the Council must be satisfied before granting approval.

PART 10: REVOCATION OF DIRECTIONS**10.1 Revocation of Directions given 3 October 1997**

Directions given by the Commissioner of Health under the *Human Reproductive Technology Act 1991* and published in the *Western Australian Government Gazette* on 3 October 1997 are revoked.

SCHEDULE 1—FORMS

FORM 1—APPLICATION FOR SPECIFIC APPROVAL OF AN INNOVATIVE CLINICAL OR LABORATORY PROCEDURE

FORM 2—APPLICATION FOR SPECIFIC APPROVAL OF RESEARCH

FORM 3—DELETED

FORM 4—DONOR INFORMATION

FORM 5—DONOR INSEMINATION INFORMATION

FORM 6—SPERM DONOR; IDENTIFYING INFORMATION

FORM 7—DI RECIPIENT IDENTIFYING INFORMATION

FORM 8—APPLICATION FOR EXTENSION OF STORAGE OF EMBRYOS FOR USE IN AN ARTIFICIAL FERTILISATION PROCEDURE

FORM 9—APPLICATION FOR EXTENSION OF STORAGE OF EMBRYOS DONATED FOR RESEARCH

FORM 10—UNDERTAKING

FORM 1

**APPLICATION FORM FOR SPECIFIC APPROVAL OF AN
INNOVATIVE CLINICAL OR LABORATORY PROCEDURE**

Name of Licensee: _____

Licence supervisor: (Full name) _____

Address: _____

Tel: _____

Fax: _____

Human Research Ethics Committee: _____

Chairman (Name)

New/modified procedure for which SPECIFIC approval is sought:

Reference No: _____ (for office use only)

The Reproductive Technology Council has granted its Specific Approval to this innovative practice.**General conditions**Unless any of the following **general conditions** are struck out, this Approval is subject to the following general conditions, and any other condition specified:

The licensee is to—

- (i) provide the Council with a progress report on the use of this procedure annually, at the time of annual reporting;
- (ii) notify the Council if the procedure is no longer used, with a full report of the findings; and
- (iii) monitor the literature and other available information about the use of similar procedures elsewhere, and ensure that Council is notified as soon as practicable of any relevant adverse findings.

Specific conditions (to be specified, if any)

Issued: (Date): _____

Signed: _____ (Chairman, Reproductive Technology Council)

DETAILS OF PROPOSAL FOR SPECIFIC APPROVAL OF AN INNOVATIVE PROCEDURE

Before completing please read the sections of the Directions relevant to research and innovative practices under WA's *Human Reproductive Technology Act 1991*.

SUMMARY (NOT MORE THAN 1,000 WORDS).

Please include—

- (1) Whether HREC approval has been sought and, if so, provide any comments on the proposal by the relevant HREC.
- (2) Evidence that, if relevant, the procedure to be adopted complies with any the standards set out in the NHMRCs 'National Statement on Ethical Conduct of Research Involving Humans' and 'Ethical guidelines on ART' and any relevant professional guidelines.
- (3) Evidence and details, whether the procedure proposed—
 - is used in other reputable, nationally or internationally recognised clinics;
 - is reported in international peer-reviewed literature indicative of safe and successful outcome, based on good research;
 - is expected to be successful in the local clinic;
 - is expected to be safe for any person likely to be affected by it, in the short and long term.
- (4) Full details of the proposed change or addition, including a copy of the information to be provided to participants to assist in their informed consent to the procedure.
- (5) Supporting documentation, references.

Please return to—

**The Executive Officer
The WA Reproductive Technology Council
First Floor C Block
189 Royal Street
EAST PERTH WA 6004**

**Telephone (08) 9222 4260
Fax (08) 9222 4236**

FORM 2

**APPLICATION FORM FOR SPECIFIC APPROVAL OF RESEARCH
UNDER WA'S *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991***

Name of Licensee: _____

Licence supervisor: (Full name) _____

Address: _____

Tel: _____

Fax: _____

Human Research Ethics Committee: _____

Chairman (Name)

Title of research project for which specific approval of Council is sought:

Date of application: _____

Reference No: _____ (for office use only)

The Reproductive Technology Council has granted its Specific Approval to this research.**General conditions**Unless any of the following **general conditions** are struck out, this Approval is subject to the following general conditions, and any other condition specified—

The licensee is to—

- (iv) provide the Council with a progress report on the project annually, at the time of annual reporting;
- (v) notify the Council if the research is terminated, with a full report of the findings; and
- (vi) monitor the literature and other available information about similar research elsewhere, and ensure that Council is notified as soon as practicable of any relevant adverse findings.

Specific conditions (to be specified, if any)

Issued (Date): _____

Signed: _____ (Chairman, Reproductive Technology Council)

Schedule 1

DETAILS OF PROPOSAL TO CARRY OUT RESEARCH UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

Before completing please read the sections of the Directions relevant to Research under WA's Human Reproductive Technology Act 1991 (Act).

SUMMARY (NOT MORE THAN 1,000 WORDS).

Please specify—

- (1) Whether research is to be carried out by the licensee or facilitated by them, and if so who will carry it out.
- (2) What is the subject of the research—
 - (a) participant(s);
 - (b) sperm or eggs intended for use in an artificial fertilisation procedure;
 - (c) eggs undergoing fertilisation; or
 - (d) embryos.

(Please note that the Council may only approve research involving human embryos that are intended for use in the reproductive technology treatment of a woman (s.14(2a)) or use of excess ART embryos referred to in s.53W(2)(b) or (f) of the Act (ie observation only, or a use prescribed in Commonwealth regulations for the purposes of s.10(2)(f) of the Research Involving Human Embryos Act 2002 (Cth)).

A licence from the NHMRC is required for any use of an excess ART embryo that is not an 'exempt use'.

- (3) Whether HREC approval has been sought and if so, provide comments made on the proposal by the relevant HREC.
- (4) Evidence that the procedure to be adopted complies with the standards set out in the NHMRCs 'National Statement on Ethical Conduct of Research Involving Humans' and 'Ethical guidelines on ART'.
- (5) If the research is embryo research of the type that the Council may approve, evidence supporting that—
 - (a) the embryo is intended for use in the reproductive technology treatment of a woman and existing scientific and medical knowledge indicates that the research is unlikely to leave the embryo unfit to be implanted in the body of a woman (s.14(2a)(a)); or
 - (b) the proposed research or use of an excess ART embryo consists of a use referred to in s.53W(2)(b) or (f) (observation only or a use prescribed in Commonwealth regulations for the purposes of s.10(2)(f) of the *Research Involving Human Embryos Act 2002* (Cth)).
- (6) Full details of the proposal.
- (7) Supporting documentation, references.

Please return to—

**The Executive Officer
The WA Reproductive Technology Council
First Floor C Block
189 Royal Street
EAST PERTH WA 6004**

**Telephone (08) 9222 4260
Fax (08) 9222 4236**

CONFIDENTIAL

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.

CONFIDENTIAL

FORM 5

DONOR INSEMINATION TREATMENT

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

Donor code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Recipient code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date of procedure	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	day		month		year		
Sperm storage licence number (<i>collector of sperm</i>)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			
Licensee or exemption number (<i>user of sperm</i>)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			

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

no clinical pregnancy	<input type="checkbox"/>
very early pregnancy loss-	
ectopic pregnancy	<input type="checkbox"/>
spontaneous abortion	<input type="checkbox"/>
blighted ovum	<input type="checkbox"/>
missed abortion	<input type="checkbox"/>
termination of pregnancy	<input type="checkbox"/>
ongoing clinical pregnancy at 8 weeks	<input type="checkbox"/>
other, specify _____	<input type="checkbox"/>
(if outcome unknown _____	
specify reasons): _____	

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

The **Storage Licensee** who collected the sperm must return this form to the Senior Policy Officer, Reproductive Technology, Health Department of WA, 189 Royal Street, East Perth WA 6004.

Ph: (08) 9222 4260 Fax: (08) 9222 4236

CONFIDENTIAL

FORM 6

SPERM DONOR: IDENTIFYING INFORMATION

This information should be sent to the Reproductive Technology 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

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
day		month		year	

Postcode of residence

--	--	--	--

Licensee number

--	--	--	--

Please return to Senior Policy Officer, Reproductive Technology, Health Department of WA,
189 Royal Street, East Perth WA 6004
Ph: (09) 222 4260 Fax: (09) 222 4236

CONFIDENTIAL

FORM 7

DI RECIPIENT IDENTIFYING INFORMATION

This information is required for each recipient of donor sperm for DI. The information should be sent to the Reproductive Technology 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 Senior Policy Officer, Reproductive Technology, Health Department of WA,
189 Royal Street, East Perth WA 6004

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

CONFIDENTIAL

FORM 8

APPLICATION FOR EXTENSION OF FROZEN EMBRYO STORAGE PERIOD FOR USE IN IVF PROCEDURE

INSTRUCTIONS

- Application can only be made by eligible participants ie those for whom the embryo was developed or, if consent for receipt after donation has been completed, the recipient(s).
- Both Part A and Part B of the application should be completed.
- Applications should be received by the Executive Officer of the Reproductive Technology Council at least one month prior to the meeting of the council preceding expiry of the current storage period.
- Approval for extension of storage cannot be granted if the storage period has already expired. Embryos are required to be removed from storage if the storage period expires and no extension has been granted.
- Please mark your envelope 'Confidential' and return this application to: the Executive Officer, Reproductive Technology Council, Health Dept of WA 189 Royal Street, East Perth WA 6004 Ph: (08) 9222 4260 Fax: (08) 9222 4236

PART A

Clinic to complete:

1. Have these embryos been granted a previous extension? yes no

2. Storage details:

Date of expiry of current storage period day month year 10 years from date embryos placed in storage in WA, or date of expiry of any later current extension

Date of Completion by Clinic day month year Licensee number

3. Treatment cycle details:

Participant ID Code Female Partner (if any)

Treatment unit ID

Treatment cycle codes: Cycle ID Fertilisation F

Date cycle commenced day month year

Date of embryo storage in WA day month year

Female DOB: day month year Partner DOB: day month year

Number of embryos affected by this expiry:

Also indicate Participant ID codes of donor/s here of applicable:

Female Partner (if any)

Health Department use only: Application Number - Code

Date of Expiry of Extended Storage Period day month year

Chairman, RTC

CONFIDENTIAL
PART B

Eligible Participant(s) to complete:

<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
day	month	year

Eligible Participant Name:	Female	Partner (if any)
name:	Family name _____	Family name _____
	Given name _____	Given name _____
Signature:	_____	_____
Address:	_____	
Postcode:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Phone Number: _____

You will be contacted by mail for notification of the outcome of your application or should we require further information in order to process your application. Your phone number will only be used to contact you if further information is required within a short time frame, we do not anticipate this happening in the majority of cases. Should we attempt to contact you discretion will be used and we will only speak to the participant or their partner.

Please indicate if there are any restrictions to the way in which you would like us to contact you.

1. Who is applying?:

(a) Both members of the eligible couple.

(b) One member only of the eligible couple.

(c) Eligible single person.

2. Are you seeking an extension with the intention of:

(a) Using the embryos for your own treatment at a later time.

(b) Donating the embryos to an eligible recipient/s.

(c) Other

3. Briefly explain your reasons for seeking an extension:

4. When do you plan to use or dispose of your embryos?

5. Signature of applicant(s)

CONFIDENTIAL

FORM 9

**APPLICATION FOR EXTENSION OF PERMITTED STORAGE PERIOD
WHERE EXCESS ART EMBRYOS HAVE BEEN DONATED FOR A USE REQUIRING
A LICENCE FROM THE NHMRC**

INSTRUCTIONS

- Application may be made by:
 - The participant(s) for whom the embryo was developed
 - Storage licensee
 - Holder of an exemption under section 28A of the *Human Reproductive Technology Act 1991* (HRT Act)
- Applications should be received by the Executive Officer of the Reproductive Technology Council at least one month prior to the meeting of the council preceding expiry of the current storage period.
- Approval for extension of storage cannot be granted if the storage period has already expired.
- Embryos are required to be removed from storage if the storage period expires and no extension has been granted.
- Please mark 'Confidential' and return to Executive Officer, Reproductive Technology Council, Health Dept of WA 189 Royal Street, East Perth WA 6004 Ph: (08) 9222 4260 Fax: (08) 9222 4236

1. Who is applying?

- (a) Participant(s) for whom the embryo is being stored
- (b) Licensee
- (c) Holder of exemption under section 28A of the HRT Act

2. Have these embryos been granted a previous extension? yes no

3. Storage details:

Date of expiry of current storage period 10 years from date embryos placed in storage in WA, or date of expiry of any later current extension

day month year

Licensee number

4. Treatment cycle details:

Participant ID Code Female Partner (if any)

Treatment unit ID

Treatment Cycle ID Fertilisation F

Date cycle commenced day month year

Date of embryo storage in WA day month year

Female DOB: day month year Partner DOB: day month year

Number of embryos affected by this expiry:

5. Briefly explain reasons for seeking extension.

Signature of applicant(s)

Health Department use only:

Application Number

9-200

-

Code

Date of Expiry of Extended Storage Period

day

month

year

Chairman, RTC

FORM 10

UNDERTAKING

EXPORT OF DONATED HUMAN REPRODUCTIVE MATERIAL FROM WESTERN AUSTRALIA (WA)

Formal undertaking between a person seeking the approval of the Reproductive Technology Council to receive this material and the WA licensee who is to export the donated human reproductive material.

This is to certify that I,

(full name, title and occupation)

of

(full address)

do undertake:

- 1. To provide the WA licensee

(Full name of licensee who is to supply the material)

within a reasonable time, with all the information that would be required if any assisted fertilisation procedure that I carry out or authorise with the donated human reproductive material were carried out in Western Australia (ie recipient code, type of treatment, date of treatment and outcome at 8 weeks after the procedure);

- 2. To provide, when requested by Register staff, recipient identifying information as required under the Act for inclusion in the WA Reproductive Technology Register;
3. To provide the recipient and their spouse/partner with all relevant information, especially regarding the Registers which have been established, prior to obtaining their consent to the procedure as set out under the Act.

I understand that if I fail to provide the required information to the licensee or the Register within a reasonable time and without good cause, the approval of Reproductive Technology Council for me to receive further material from the licensee may be withdrawn.

.....(Date).....

(Signature of applicant)

TO OBTAIN APPROVAL THE APPLICANT FOR APPROVAL SHOULD RETURN THE SIGNED ORIGINAL OF THIS UNDERTAKING TO THE RELEVANT WA LICENSEE. THE LICENSEE SHOULD THEN CONTACT THE REPRODUCTIVE TECHNOLOGY COUNCIL SEEKING ITS APPROVAL, IN WRITING, TO EXPORT THE MATERIAL TO THE APPLICANT, ENCLOSING A COPY OF THIS UNDERTAKING.

Schedule 2

Some of the details required in this section are not necessary for sperm donors, as this information is collected elsewhere (ie Form 4- Donor Non-Identifying Information). These fields are Place of Birth and Occupation. It is at the clinics discretion whether they include this information here or leave it blank.

No 1	No 2	Name	Notes	Type & Length	Coding
1	1	Unit	This is the unit number supplied by the NPSU. This field replaces the old licensee number.	Num-3	3 digit IVF code provided by the NPSU
2	2	ID Code	This is the participant or donor id. This is a unique ID for the patient. This can take whatever form the Unit wishes.	Char-8	
	3	Gender	This is the gender of the participant or donor	Char-1	F= Female M= Male
	4	Surname		Char-50	
	5	Given Name 1	First given name of the participant/donor	Char-50	
	6	Given Name 2	Second given name and any other given names.	Char-50	Leave blank if none
	7	Maiden Name	Maiden name of female participant.	Char-50	Leave blank if none
	8	Other Surname	Any other surnames (eg from previous marriage, name change) the participant may have.	Char-50	Leave blank if none
	9	DOB	This is the date of birth of the participant/donor. The RT register has the capacity to use these fields to calculate the NPSU fields mdob, pdob & don_age.	Date-10	dd/mm/yyyy format
	10	POB	This is the place of birth. Where this is Australia, please name the state or territory. If this is outside Australia only the country is required.	Char-50	
	11	Occupation	This is the occupation of the participant/donor. If this is housework, home duties etc please use the term home duties.	Char-50	
	12	Postcode	This is the postcode where the participant/donor resides. Please note if the patient usually resides overseas and is just receiving treatment in Perth please use 1111 as the postcode.	Char-6	If usually resides overseas please use 1111
	13	Other IVF	Whether the participant has undertaken IVF treatment at another clinic. Can be left blank for donors and recipients of donor insemination treatment.	Char-1	Y= Yes N= No
	14	Other IVF Where	This is the name of the clinic where the participant has previously had treatment. Can be left blank for donors and recipients of donor insemination treatment.	Char-30	

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
	15	Duration of Infertility	This is the number of years the person has been trying to get pregnant without success. Can be left blank for donors and recipients of donor insemination treatment.	Num-2	
	16	Treatment Reason	This is the reason IVF or Donor Insemination is being pursued. Choose from the following reasons. If other is chosen please specify the reason for treatment.	Char-20	I= Own Infertility SD= Sperm Donor OD= Oocyte Donor G= Genetic Disease Other= specify

PART 2: TREATMENT CYCLE DATA

Treatment cycle information is a combination of NPSU data field and RT Register fields. All fields from the NPSU data structure are included.

The cycles to be included are the same as that required by the NPSU. They are as follows—

- All **Oocyte Pick Ups**
- All **Cancelled cycles where FSH has been administered**
- All Cycles where **frozen embryos are thawed** regardless of the intention or outcome of the thawing process
- All cycles where artificial insemination is performed using donated sperm (ie **donor insemination**)
- Each occasion where embryos are either donated or moved into or out of an IVF Unit from a different unit

No 1	No 2	Name	Notes	Type & Length	Coding
1	1	Unit	This is the unit number supplied by the NPSU. This field replaces the old licensee number.	Num-3	3 digit IVF code provided by the NPSU
2	2	Site	Same as the NPSU field site ie site of the most significant part of the treatment..	Num-2	2 digit code for each clinic 00= Main site 01-99= Satellite sites (NPSU codes)
3	3	Pat_ID	This is the female participants ID code. This is a unique ID for the patient. This can take whatever form the Unit wishes.	Char-8	
N	76	Partner ID	This is the identification code of the partner of the female participant.. This should also be completed for lesbian couples.	Char-8	
4	4	Mdob	Patient date of birth. Leave blank where patient is an oocyte or embryo donor and insert the age in completed years in Don_age (field 6).	Date-10	dd/mm/yyyy format
5	5	Pdob	That is the husband/partners date of birth. Can be left blank if single, lesbian or oocyte/embryo donor.	Date-10	dd/mm/yyyy format
6	6	Don_age	Age of the egg or embryo donor. Completed in years at time of donation. This item must be completed for a donor oocyte or donor embryos cycle but otherwise must be left blank.	Num-2	99= not known
7	7	N_13200	The number of billed Australian Medicare item 13200.	Num-2	

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
8	8	Ci_tube	Answer "yes" if in the opinion of the treating clinician or clinic there is significant tubal disease present. Otherwise answer "no". In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Char-1	N= No Y= Yes To be filled in for recipient not donor
9	9	Ci_endo	Answer "yes" if in the opinion of the treating clinician or clinic there is significant endometriosis contributing to this couple's subfertility. Otherwise answer no. In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Char-1	N= No Y= Yes To be filled in for recipient not donor
10	10	Ci_male	Answer "yes" if in the opinion of the treating clinician or clinic there is a significant male problem. Otherwise answer "no". In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Char-1	N= No Y= Yes To be filled in for recipient not donor
11	11	Ci_oth	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to any other factors apart from female age, tubal disease, male factor, endometriosis or sterilization. Possible examples could include fibroids, ovulation disorders or premature ovarian failure. If there is no clinical subfertility (eg egg donor, preimplantation genetic diagnosis or other non-fertility reason for ART), answer "No". In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Char-1	N= No Y= Yes To be filled in for recipient not donor
N	77	Ci_oth specify	This is a description of the "Other" reason for infertility. If Ci_Oth is marked "yes" this field must be completed, otherwise leave blank.	Char-50	
12	12	Ci_unex	Answer "yes" if in the opinion of the treating clinician or clinic there is clinical subfertility without any apparent explanation. If there is no clinical subfertility (eg egg donor, preimplantation genetic diagnosis or other non-fertility reason for ART), answer "No". In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Char-1	N= No Y= Yes To be filled in for recipient not donor

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
	78	Ci_FSter	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to tubal ligation or medical sterilisation of the female participant. Otherwise answer "no". In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Char-1	N= No Y= Yes To be filled in for recipient not donor
	79	Ci_Mster	Answer "yes" if in the opinion of the treating clinician or clinic there is subfertility due to vasectomy or medical sterilisation of the male partner. Otherwise answer "no". In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Char-1	N= No Y= Yes To be filled in for recipient not donor
13	13	N_prless	This is the number of all known pregnancies less than 20 weeks in the female partner regardless of whether by ART or by a different partner. In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Num-2	0= no previous pregnancies <20 wks 3= 3 previous pregnancies < 20 wks To be filled in for recipient not donor
14	14	N_prmore	This is the number of all known pregnancies reaching 20 weeks or more in the female partner regardless of whether by ART or by a different partner. In donor oocyte/embryo cycles this field should be left blank for the donor, and completed for the recipient.	Num-2	0= no previous pregnancies <20 wks 3= 3 previous pregnancies < 20 wks To be filled in for recipient not donor
15	15	Cycle_id	This item number is unique to this cycle and will only be used to facilitate queries about the data. The cycle ID must be unique to the cycle not just the patient.	Char-10	
16	16	Cycle date	This field must be completed for all cycles. For treatment cycles this is according to the Medicare definition and is the date of LMP for unstimulated cycles or, where FSH is used, the first date of FSH administration. For cycles where the only process is movement or disposal of embryos, this is the date of embryo movement. This date defines the year in which a cycle is reported to the NPSU.	Date-10	

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
	80	Procedure type	That is the type of procedure. That is— <ul style="list-style-type: none"> • Donor Insemination (DI) • Gamete Intra-Fallopian Tube Transfer (GIFT) • OPU with or without fresh transfer or egg fert (IVF) • Frozen embryo transfer (FET) • OPU with fresh and frozen emb transfer (IVF+FET) • GIFT with simultaneous FET (GIFT+FET) • Cancelled OPU (Can OPU) • Cancelled FET (Can FET) • Embryo Move ie embryo disposal or export • Embryo Move for Research 		Acceptable abbreviations— DI; GIFT; IVF; FET; IVF+FET; GIFT+FET; Can OPU, Can FET, Emb Move; Research
17	17	Surr	Is this procedure part of a surrogacy arrangement	Char-1	N= No Y= Yes
18	18	Ov_Stim	Was injectable FSH stimulation administered. Does not include clomiphene or hCG alone unless FSH was also administered.	Char-1	N= No Y= Yes
19	19	Di_insem	Date of first donor insemination this cycle. Leave this field blank if no insemination was done or if donated sperm was only used for AR procedure.	Date-10	dd/mm/yyyy format
	81	Drug 1	Drug administered one, that is the name of the first drug administered. Previously this information was divided into down regulation, stimulation, luteal support and pregnancy support, this distinction is no longer required. This should include only drugs which are used to regulate a cycle/ pregnancy.	Char-30	Leave blank if no drugs
	82	Drug 1 Dose	This is the total dose of Drug 1. The dose is that administered over the entire cycle/pregnancy and is not divided into phases (ie down regulation, stimulation, luteal support and pregnancy support).	Num-10	Leave blank if no drugs
	83	Drug 1 Days	This is the total number of days Drug 1 was administered for over the entire cycle/pregnancy.	Num-3	Leave blank if no drugs
	84	Drug 2	Drug administered two, that is the name of the second drug administered.	Char-30	Leave blank if no drugs
	85	Drug 2 Dose	This is the total dose of Drug 2. The dose is that administered over the entire cycle/pregnancy and is not divided into phases (ie down regulation, stimulation, luteal support and pregnancy support).	Num-10	Leave blank if no drugs

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
	86	Drug 2 Days	This is the total number of days Drug 2 was administered for over the entire cycle/pregnancy.	Num-3	Leave blank if no drugs
	87	Drug 3	Drug administered three, that is the name of the third drug administered.	Char-30	Leave blank if no drugs
	88	Drug 3 Dose	This is the total dose of Drug 3. The dose is that administered over the entire cycle/pregnancy and is not divided into phases (ie down regulation, stimulation, luteal support and pregnancy support).	Num-10	Leave blank if no drugs
	89	Drug 3 Days	This is the total number of days Drug 3 was administered for over the entire cycle/pregnancy.	Num-3	Leave blank if no drugs
	90	Drug 4	Drug administered four, that is the name of the fourth drug administered.	Char-30	Leave blank if no drugs
	91	Drug 4 Dose	This is the total dose of Drug 4. The dose is that administered over the entire cycle/pregnancy and is not divided into phases (ie down regulation, stimulation, luteal support and pregnancy support).	Num-10	Leave blank if no drugs
	92	Drug 4 Days	This is the total number of days Drug 4 was administered for over the entire cycle/pregnancy.	Num-3	Leave blank if no drugs
	93	Drug 5	Drug administered five, that is the name of the fifth drug administered.	Char-30	Leave blank if no drugs
	94	Drug 5 Dose	This is the total dose of Drug 5. The dose is that administered over the entire cycle/pregnancy and is not divided into phases (ie down regulation, stimulation, luteal support and pregnancy support).	Num-10	Leave blank if no drugs
	95	Drug 5 Days	This is the total number of days Drug 5 was administered for over the entire cycle/pregnancy.	Num-3	Leave blank if no drugs
	96	Drug 6	Drug administered six, that is the name of the sixth drug administered.	Char-30	Leave blank if no drugs
	97	Drug 6 Dose	This is the total dose of Drug 6. The dose is that administered over the entire cycle/pregnancy and is not divided into phases (ie down regulation, stimulation, luteal support and pregnancy support).	Num-10	Leave blank if no drugs
	98	Drug 6 Days	This is the total number of days Drug 6 was administered for over the entire cycle/pregnancy.	Num-3	Leave blank if no drugs

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
	99	Retrieval General Anaesthetic	Whether General Anaesthetic was administered for OPU.	Char-1	N= No Y= Yes
	100	Retrieval Antibiotics	Whether Antibiotics were administered OPU.	Char-1	N= No Y= Yes
	101	Retrieval Other Medication	Whether any other medication was used OPU. This should include sedatives.	Char-10	Specify medication type
	102	Transfer General Anaesthetic	Whether General Anaesthetic was administered for embryo transfer.	Char-1	N= No Y= Yes
	103	Transfer Antibiotics	Whether Antibiotics were administered for embryo transfer.	Char-1	N= No Y= Yes
	104	Transfer Other Medication	Whether any other medication was used for embryo transfer. This should include sedatives.	Char-10	Specify medication type
N	105	OHSS	Whether there was any ovarian hyper stimulation, and if so the severity. Refer to protocol manual for definitions of severity.		Choices— None Mild Moderate Severe
	106	Retrieval Method	Method of OPU. Cancelled cycles are those where the cycle is stopped prior to any attempt to retrieve oocytes, if oocyte retrieval is attempted and no eggs are retrieved the cycle is not considered cancelled. In this case the method of attempted retrieval should be entered. Choose from the listed methods of retrieval. If other is chosen please specify the reason for treatment.	Char-20	Choices— Laparoscopy T/V Ultrasound Cancelled Other Specified
20	20	Opu_date	The date that oocyte retrieval was performed. Leave blank if no OPU was performed. If it is known that an OPU has taken place but the exact date is unknown enter 01/01/2001.	Date-10	Please leave blank if no OPU performed. dd/mm/yyyy format
	21	N_eggs	Number of oocytes which are retrieved at OPU. Include any immature oocytes that are identified.	Num-2	0= no eggs retrieved
N	107	N_eggsexp	Number of oocytes which donated for research or quality assurance.	Num-2	0= no eggs used for experiments/ QA
N	108	N_eggsdisc	Number of oocytes which were discarded as they were abnormal or immature.	Num-2	0= no eggs discarded
N	109	N_eggsfroz	Number of oocytes which were frozen.	Num-2	0= no eggs frozen
22	22	N_donated	Number of oocytes donated to someone else.	Num-2	0= no eggs donated
23	23	N_recvd	Number of eggs received from someone else.	Num-2	0= no eggs received
24	24	N_gift	Number of eggs replaced in a gift procedure	Num-2	0= GIFT not performed

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
N	110	FertCode	If fertilisation through IVF or ICSI was attempted a code should be attributed to the fertilisation procedure. If there was no fertilisation attempted this field may be left blank. This field is the same as the old fertilisation code used by the RT Register. It should be coded as FXXXX. The fertilisation code must be unique to the fertilisation not just the patient. Required when a fertilisation is attempted or for transfer of embryos (eg FET or embryo move), otherwise leave blank.	Char-8	
25	25	N_insem	Number of eggs treated with IVF, do not include ICSI oocytes	Num-2	0= IVF not performed
26	26	N_ICSI	Number of eggs treated with ICSI	Num-2	0= ICSI not performed
N	111	EggsNotFert	Number of oocytes not fertilised	Num-2	0= All eggs fertilised
N	112	EmbryoFresh	Number of embryos fresh transferred	Num-2	0= no embryos fresh transferred
39	39	N_clfroz	Number of zygotes or cleavage stage embryos (i.e. <4 days since fertilisation) frozen.	Num-2	0=No cleaved embryos frozen
40	40	N_blfroz	Number of blastocyst embryos (i.e. >4 days since fertilisation) frozen.	Num-2	0=No blastocyst embryos frozen
41	41	emdonexp	This field serves two purposes: (1) Records the number of embryos that are to be donated to someone else (donor cycle); (2) Records the number of embryos to be exported from the current unit to another unit	Num-2	0= No embryos donated/exported
N	113	EmbExpLic	If embryos are exported to another unit, please specify receiving units NPSU code or Licensee number or the Licence number of a NHMRC embryos research approval.		Leave blank if no export
N	114	EmbryoAbnorm	Number of embryos that were considered abnormal and allowed to succumb	Num-2	0= No abnormal embryos
N	115	EmbryoSurplus	Number of embryos that were normal however excess to patient needs therefore allowed to succumb	Num-2	0= No surplus normal embryos discarded
27	27	Sp_site	Site of sperm extraction. That is ejaculated, epididymal, testicular or bladder.	Char-1	E= Ejaculate T= Testicular P= Epididymal O= Other
28	28	Sp_persn	Person whose sperm was used in insemination. To be filled out for donor insemination or use of donor sperm in IVF	Char-1	H= Husband K= Known Donor A= Anonymous Donor

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
N	116	SpDonorLic	If a sperm donor was used the storage licensee from whom that sperm came from is required. The storage licensee number is provided to clinics by the Commissioner of Health. To be filled out for donor insemination or use of donor sperm in IVF	Char-3	002=Concept 004=Pivet 009=Keogh 015=Hollywvood 017=Joondalup
N	117	SpDonorID	If a sperm donor was used the sperm donors id is required. To be filled out for donor insemination or use of donor sperm in IVF	Char-8	
N	118	SpPrepWashing	If washing was used in sperm preparation	Char-1	N= No Y= Yes
N	119	SpPrepGradient	If gradient method was used in sperm preparation	Char-1	N= No Y= Yes
N	120	SpPrepSwimup	If swim up was used for sperm preparation	Char-1	N= No Y= Yes
N	121	SpPrepOther	Any other preparations methods that were used. Include Isolate here. The Other method should be specified	Char-20	Specify Other method Eg Isolate
N	122	ChemStim	If chemical stimulation was used please specify the name of the chemical stimulant	Char-20	Specify chemical stimulant eg. pentoxifylline
N	123	Manipulation	If a micro manipulation technique was used to assist in fertilisation eg. PZD, SUZI please specify the technique used here. Not necessary to include ICSI here.	Char-20	Specify micro manipulation technique
29	29	N_fert	Number of eggs fertilised normally. The critical issue is the opinion of the treating embryologist. Thus even if two pronuclei are not seen but cleavage occurs, provided the embryologist considers this to be a normal fertilisation then it should be included.	Num-2	0= No normally fertilised embryos produced.
30	30	PGD	Answer yes where PGD in any form has been performed on any of the embryos. Otherwise answer no. If "NO" leave PGD fields blank.	Char-1	N= No Y= Yes
	132	NumPGD	Number of embryos biopsied for genetic testing.	Num-2	
	133	N_Aneup_Test	Number of embryos tested for aneuploidy.	Num-2	
	134	N_SGD_Test	Number of embryos tested for specific gene disorder.	Num-2	
	135	SGD_Specify	Please specify the name of the specific gene disorder tested (eg cystic fibrosis).	Char-20	Specify SGD
	136	N_PGD_Normal	Number of embryos considered normal after testing.	Num-2	
	137	N_Aneup	Number of embryos with aneuploidy.	Num-2	

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
	138	N_SGD	Number of embryos with the specific gene disorder tested for.	Num-2	
31	31	Ass_hatc	Answer yes where assisted hatching in any form has been performed on any of the embryos. Otherwise answer no.	Char-1	N= No Y= Yes
32	32	Emrecimp	This field serves two purposes: (1) Records the number of embryos that are to be received from donation (recipient cycle); (2) Records the number of embryos to be imported into the current unit from another unit.	Num-2	0= No embryos received/imported
33	33	N_clthaw	Number of zygotes or cleavage stage embryos thawed with the intention of performing an embryo transfer if they survive.	Num-2	0= No cleaved embryos thawed
34	34	N_blthaw	Number of blastocysts (ie greater than 4 days culture from fertilisation) thawed with intention of performing an embryo transfer if they survive.	Num-2	0= No blastocyst embryos thawed
35	35	Et_date	This is the date of embryos transfer. To be left blank if there was no embryo transfer. If it is known that an embryo transfer has taken place but the exact date is unknown enter 01/01/2001	Date-10	dd/mm/yyyy format
N	124	FertLicensee1	That is the clinic/unit ID of the clinic where the fertilisation took place. Either the NPSU code or the Licensee number may be entered. This field is only required where there is embryo transfer, disposal or export, otherwise it may be left blank.	Num-3	NPSU unit code or RTC licensee number
N	125	FertCode1	This is the code attributed to the fertilisation procedure. This field is only required where there is embryo transfer, disposal or export, otherwise it may be left blank.	Char-8	
N	126	FertLicensee2	That is the clinic/unit ID of the clinic where the fertilisation took place. Either the NPSU code or the Licensee number may be entered. This field is only required where there is embryo transfer, disposal or export, otherwise it may be left blank.	Num-3	NPSU unit code or RTC licensee number
N	127	FertCode2	This is the code attributed to the fertilisation procedure. This field is only required where there is embryo transfer, disposal or export, otherwise it may be left blank.	Char-8	

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
N	128	DonorOwnEmbryos	Whether donor embryos or a couples own embryos were used in embryo transfer. Please note embryos created with donor oocytes and/or sperm intended for the participants in question should be marked as own.	Char-1	D=Donor O=Own
N	129	N_clunsuitable	Number of zygotes or cleavage stage embryos thawed that are unsuitable for transfer.	Num-2	0= no cleaved embryos unsuitable
N	130	N_blunsuitable	Number of blastocysts (ie greater than 4 days culture from fertilisation) thawed that are unsuitable for transfer.	Num-2	0= no blastocysts unsuitable
36	36	N_emb_et	Number of zygotes of cleavage stage embryos (i.e. <4 days since fertilisation) transferred.	Num-1	0= no cleaved embryos transferred.
37	37	N_bl_et	Number of blastocyst embryos (i.e. >4 days since fertilisation) transferred.	Num-1	0= no blastocyst embryos transferred.
38	38	Emb_icsi	Were any of the transferred embryos fertilised by ICSI?	Char-1	N= No Y= Yes
N	131	Transfer Site	This is the site of embryo transfer, ie either uterine or fallopian tube	Char-1	U= Uterine T= Tubal
42	42	Emb_disp	The number of frozen embryos disposed of in accordance with patient or Government request.	Num-2	0= No usable embryos discarded.
43	43	Pr_clin	Whether there was a clinical pregnancy. A clinical pregnancy must fulfil one of the following criteria: 1. Known to be ongoing at 20 weeks; 2. Evidence by ultrasound of an intrauterine sac (with or without fetal heart); 3. Examination of products of conception reveal chorionic villi; or 4. A definite ectopic pregnancy that has been diagnosed laparoscopically or by ultrasound.	Char-1	N= No Y= Yes
44	44	Pr_end_dt	Date the pregnancy ended. This is the date on which delivery, miscarriage or termination takes place. This date must eventually be completed if the answer to pr_clin is "yes". If the exact date is unknown, enter an approximate guess. Where multiple birth occur over more than one date, enter the date of the first baby born.	Date-10	dd/mm/yyyy

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
45	45	N_fh	Number of fetal hearts seen on first ultrasound (intrautereine only)	Num-2	0= Ectopic Pregnancy 8= US not performed 9= Num FH unknown
46	46	Pr_ectop	If this pregnancy is an ectopic pregnancy or a combined ectopic and uterine (heterotopic) pregnancy, enter "yes".	Char-1	N= No Y= Yes
47	47	Pr_top	Elective termination of pregnancy. Do not include pregnancies where a planned fetal reduction of a multiple pregnancy results in subsequent unintended miscarriage, or a pregnancy where there has been an IUD requiring induced delivery. Give reasons for TOP in Abn_less (field 49).	Char-1	N= No Y= Yes
48	48	Pr_reduc	Where selective reduction was performed due to fetal abnormality, give details in Abn_less (field 49).	Char-1	N= No Y= Yes
49	49	Abn_less	This field applies to elective terminations of pregnancy and fetal reductions due to fetal abnormality. Specify as much detail as possible. Please mail/fax supporting documentation eg. TOP form, autopsy report.	Text-250	Leave blank where no fetal abnormality. Do not insert "nil" or "none"
50	50	Mat_comp	Maternal complications of pregnancy. Insert as much detail as possible. Please mail or fax supporting documentation eg. discharge form	Text-250	Leave blank where no complications. Do not insert "nil" or "none"
51	51	N_deliv	Number of babies delivered after 20 weeks. Include all live born and stillborn babies. If N_fh (number of fetal hearts seen) >0 this field must be completed.	Num-1	0= No babies born, all fetuses aborted
52	52	CS	Caesarean delivery. Doesn't matter whether CS was planned or emergency. If any of a multiple birth are a caesarean section delivery, answer yes.	Char-1	N= No Y= Yes
53	53	Bab1_out	Outcome of first baby born.	Char-1	S= stillbirth L= live birth/survived N= Livebirth but died <28 days (neonatal death)
54	54	Bab1_sex	Gender of first baby born	Char-1	M= Male F= Female
55	55	Bab1_wt	Birth weight in grams of first baby born	Num-4	750= 750g 559999= Not stated

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
56	56	Bab1_abn	Abnormality in the first baby born. Put as much details as known about congenital malformation. Please mail/fax supporting documentation eg. birth defect form, autopsy report, doctors letter.	Text-250	Leave blank where no abnormality. Do not insert "nil" or "none".
57	57	Bab1_nnd	Date of Neonatal death of first baby born. Leave blank if no neonatal death. If it is known that a neonatal death has taken place but the exact date is unknown enter 01/01/2001.	Date-10	dd/mm/yyyy
58	58	Bab2_out	Outcome of second baby born.	Char-1	S= stillbirth L= live birth/ survived N= Livebirth but died <28 days (neonatal death)
59	59	Bab2_sex	Gender of second baby born	Char-1	M= Male F= Female
60	60	Bab2_wt	Birth weight in grams of second baby born	Num-4	750= 750g 9999= Not stated
61	61	Bab2_abn	Abnormality in the second baby born. Put as much details as known about congenital malformation. Please mail/fax supporting documentation eg. birth defect form, autopsy report, doctors letter.	Text-250	Leave blank where no abnormality. Do not insert "nil" or "none".
62	62	Bab2_nnd	Date of Neonatal death of second baby born. Leave blank if no neonatal death. If it is known that a neonatal death has taken place but the exact date is unknown enter 01/01/2001.	Date-10	dd/mm/yyyy
63	63	Bab3_out	Outcome of third baby born.	Char-1	S= stillbirth L= live birth/ survived N= Livebirth but died <28 days (neonatal death)
64	64	Bab3_sex	Gender of third baby born	Char-1	M= Male F= Female
65	65	Bab3_wt	Birth weight in grams of third baby born	Num-4	750= 750g 9999= Not stated
66	66	Bab3_abn	Abnormality in the third baby born. Put as much details as known about congenital malformation. Please mail/fax supporting documentation eg. birth defect form, autopsy report, doctors letter.	Text-250	Leave blank where no abnormality. Do not insert "nil" or "none".
67	67	Bab3_nnd	Date of Neonatal death of third baby born. Leave blank if no neonatal death. If it is known that a neonatal death has taken place but the exact date is unknown enter 01/01/2001.	Date-10	dd/mm/yyyy

Schedule 2

No 1	No 2	Name	Notes	Type & Length	Coding
68	68	Bab4_out	Outcome of fourth baby born.	Char-1	S= stillbirth L= live birth/ survived N= Livebirth but died <28 days (neonatal death)
69	69	Bab4_sex	Gender of fourth baby born	Char-1	M= Male F= Female
70	70	Bab4_wt	Birth weight in grams of fourth baby born	Num-4	750= 750g 9999= Not stated
71	71	Bab4_abn	Abnormality in the fourth baby born. Put as much details as known about congenital malformation. Please mail/fax supporting documentation eg. birth defect form, autopsy report, doctors letter.	Text-250	Leave blank where no abnormality. Do not insert "nil" or "none".
72	72	Bab4_nnd	Date of Neonatal death of fourth baby born. Leave blank if no neonatal death. If it is known that a neonatal death has taken place but the exact date is unknown enter 01/01/2001.	Date-10	dd/mm/yyyy
73	73	Morb_adm	Answer yes if the female partner is admitted to hospital with any condition (excluding any pregnancy-related issues, such as an ectopic pregnancy) that could be in any way related to fertility treatment, eg. OHSS, infection or bleeding after eg. pick up.	Char-1	Y= Yes
74	74	Mrb_ohss	If the cause of the morbidity is OHSS answer yes. To be filled out only if morb_adm (field 73) is yes otherwise leave blank.	Char-1	Y= Yes N= No Leave this field blank if no morbidity.
75	75	Morb_inf	Provide details of the morbidity. Put in as much detail as known about the cause of morbidity. Leave this field blank if Morb_adm (field 73) is not yes.	Text-250	Leave this field blank if no morbidity.

SCHEDULE 3—ANNUAL REPORTING

PART 1	ANNUAL REPORTING BY EXEMPT PRACTITIONERS
PART 2	ANNUAL REPORTING BY PRACTICE LICENSEES
PART 3	ANNUAL REPORTING BY STORAGE LICENSEES ABOUT DONATED SEMEN
PART 4	ANNUAL REPORTING BY STORAGE LICENSEES ABOUT EMBRYOS
PART 5	ANNUAL REPORTING ABOUT COUNSELLING

PART 1

ANNUAL REPORTING BY EXEMPT PRACTITIONERS

The following pro-forma should be used for reporting, and if applicable, a 'nil' return must still be shown on the pro-forma.

a) Your Exemption number: E

b) Your Name: _____

c) Number and details of IUI procedures carried out during the year:

Source of semen	Ovulation induction	Number of (#) IUI procedures carried out	Number of (#) resulting early pregnancies (sacs initial US): singleton, twin, triplet etc.	Number of (#) resulting ongoing pregnancies: singleton, twin, triplet etc
DONOR	Nil	# =	1 # =	1 # =
			2 # =	2 # =
			3 # =	3 # =
			4 # =	4 # =
			>4 # =	>4 # =
			Unknown Plurality # =	Unknown Plurality # =
	Clomid only		1 # =	1 # =
			2 # =	2 # =
			3 # =	3 # =
			4 # =	4 # =
			>4 # =	>4 # =
			Unknown Plurality # =	Unknown Plurality # =
	+Gonadotrophins		1 # =	1 # =
			2 # =	2 # =
			3 # =	3 # =
			4 # =	4 # =
			>4 # =	>4 # =
			Unknown plurality # =	Unknown Plurality: # =
HUSBAND	Nil		1 # =	1 # =
			2 # =	2 # =
			3 # =	3 # =
			4 # =	4 # =
			>4 # =	>4 # =
			Unknown Plurality # =	Unknown Plurality # =
	Clomid only		1 # =	1 # =
			2 # =	2 # =
			3 # =	3 # =
			4 # =	4 # =
			>4 # =	>4 # =
			Unknown Plurality # =	Unknown Plurality # =
	+Gonadotrophins		1 # =	1 # =
			2 # =	2 # =
			3 # =	3 # =
			4 # =	4 # =
			>4 # =	>4 # =
			Unknown Plurality # =	Unknown Plurality # =

PART 2**ANNUAL REPORTING BY PRACTICE LICENSEES**

The following pro-forma should be used for reporting. All sections must be completed with a 'nil' return for those sections that are not applicable.

1. About 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;
 - Micro-manipulation, with a breakdown by type (eg ICSI);
 - sperm retrieval, with a breakdown by location (eg epididymis);
 - Fallopian embryo transfer;
 - Blastocyst culture;
 - PGD;
 - Assisted hatching.

(ii) Frozen Embryo Transfer (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;
 - Blastocyst culture;
 - PGD;
 - Assisted hatching.

(iii) 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. About morbidity associated with artificial fertilisation procedures

- (i) The following information on serious morbidity associated with artificial fertilisation procedures carried out under the licence—
- (a) For each case considered by the clinician to indicate severe hyperstimulation syndrome, provide
- FID #;
- treatment cycle ID# (for comparative linkage to the HMDS to find length of hospitalisation);
- the number of follicles over 12mm noted at any ultrasound; and
- any additional evidence of ascites (clinical or ultrasound) or an abnormal haematocrit; and
- (b) For all cases of severe pelvic infection, (defined as infection serious enough to require hospitalisation of a woman for >48 Hours within the time limit of the global rebate), provide FID# and treatment cycle ID# (also for comparative purposes);
- (c) For any other case of severe morbidity in either the male or female participant requiring hospitalisation for >48 hours within the time limit of the global rebate, provide FID# or MID#, treatment cycle ID#, and a brief summary of the case;
- (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) 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, micro-manipulation, IUI, tubal transfer etc).

5. About intra-uterine insemination procedures.

Number and details of IUI procedures carried out during the year—

Source of semen	Ovulation induction	Number of (#) IUI procedures carried out	Number of (#) resulting early pregnancies (sacs initial US): singleton, twin, triplet etc.	Number of (#) resulting ongoing pregnancies: singleton, twin, triplet etc	
DONOR	Nil	# =	1 # =	1 # =	
			2 # =	2 # =	
			3 # =	3 # =	
			4 # =	4 # =	
			>4 # =	>4 # =	
			Unknown Plurality # =	Unknown Plurality # =	
			Unknown Plurality # =	Unknown Plurality # =	
	Clomid only			1 # =	1 # =
				2 # =	2 # =
				3 # =	3 # =
				4 # =	4 # =
				>4 # =	>4 # =
				Unknown Plurality # =	Unknown Plurality # =
				Unknown Plurality # =	Unknown Plurality # =
	+Gonadotrophins			1 # =	1 # =
				2 # =	2 # =
				3 # =	3 # =
				4 # =	4 # =
				>4 # =	>4 # =
				Unknown plurality # =	Unknown Plurality: # =
				Unknown plurality # =	Unknown Plurality: # =

Schedule 3

Source of semen	Ovulation induction	Number of (#) IUI procedures carried out	Number of (#) resulting early pregnancies (sacs initial US): singleton, twin, triplet etc.	Number of (#) resulting ongoing pregnancies: singleton, twin, triplet etc
HUSBAND	Nil		1 #=	1 #=
			2 #=	2 #=
			3 #=	3 #=
			4 #=	4 #=
			>4 #=	>4 #=
			Unknown Plurality #=	Unknown Plurality #=
	Clomid only		1 #=	1 #=
			2 #=	2 #=
			3 #=	3 #=
			4 #=	4 #=
			>4 #=	>4 #=
			Unknown Plurality #=	Unknown Plurality #=
	+Gonadotrophins		1 #=	1 #=
			2 #=	2 #=
			3 #=	3 #=
			4 #=	4 #=
			>4 #=	>4 #=
			Unknown Plurality #=	Unknown Plurality #=

6. Additional information

- (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.

PART 3**ANNUAL REPORTING BY STORAGE LICENSEES ABOUT DONATED SEMEN**

The following pro-forma should be used for reporting. All sections must be completed with a 'nil' return for those sections that are not applicable.

About semen stored for donation

- (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.

PART 4**ANNUAL REPORTING BY STORAGE LICENSEES ABOUT EMBRYOS**

The following pro-forma should be used for reporting. All sections must be completed with a 'nil' return for those sections that are not applicable.

About embryo storage

- (i) Total number of embryos put into storage in the previous financial year, from July 1 to June 30 with breakdown by;
 - # embryos put into storage following IVF carried out by the licensee;
 - # embryos put into storage following transfer from another WA Licensee (with Licensee codes); and
 - # embryos put into storage following transfer 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 breakdown by;
 - # embryos removed from storage and thawed for FET;
 - # embryos removed from storage and allowed to succumb;
 - # embryos removed from storage and transferred to other WA Storage Licensees (with Licensee codes);
 - # embryos removed from storage and transferred out of the state for IVF treatment, with information as to where these were sent, and why;
 - # embryos transferred under a licence granted by the NHMRC Embryo Research Licensing Committee with NHMRC Licence number;
 - # embryos removed from storage for a use by the Storage licensee carried out under a licence granted by the NHMRC Licensing Committee with NHMRC Licence number;
- (iii) Total number of embryos in storage at the end of the financial year, June 30.

PART 5**ANNUAL REPORTING ABOUT COUNSELLING**

The attached Counselling Reporting Form should be used for reporting. All sections must be completed with a 'nil' return for those sections that are not applicable.

Guidelines for completion of Counselling Reporting Form

The reporting form is divided into three sections.

1. The first section relates to all counselling provided in the clinic in one year. Information is required on the type of counselling provided and the total number of sessions attended by couples and individuals. It also provides information about counselling attended by donors.
2. The second section relates to the number of counselling sessions attended by either couples or individuals. Information is required on the number of couples or individuals who attended one only counselling session. Information is also required on couples/individuals who attended more than one session.
3. The third section relates to other activities provided by counsellors.

People seeking treatment

Treatment can be divided into categories, as follows—

- *In vitro* Fertilisation (IVF) / Gamete Intra Fallopian Tube (GIFT), using own or donated gametes/embryos;
- Intra Cytoplasmic Sperm Injection (ICSI);
- Intra Uterine Insemination/artificial insemination, using own or donated gametes.

Donors

Donors can be divided into three categories, namely—

- Sperm donors;
- Egg donors;
- Embryo donors.

Donors may be known or unknown to the recipients of their donations.

Section 1 Type of counselling

The counselling provided to people undergoing artificial fertilisation treatment can be divided into specific types. These can range from the provision of information and assistance with decision-making to intensive therapeutic services. It is important to categorise the counselling services that are provided in the clinics. Four categories/types of counselling have been identified, namely:

1. information counselling and assistance with decision making;
2. support counselling;
3. therapeutic counselling; and
4. counselling to help with decision making on whether to discontinue treatment.

1.1 Information counselling

Information counselling involves counselling for issues associated with treatment. It aims to enable the person to understand the implications of their proposed course of treatment, for themselves, for their family, and for any children likely to be born as a result of these treatments. It would also assist people in deciding to go ahead with treatment and the type of treatment that would suit them best. It could include counselling prior to and during treatment.

1.2 Support counselling

Support counselling aims to give emotional support at times of particular stress, for example, when there is failure to achieve a pregnancy. This would generally involve one session of counselling.

1.3 Therapeutic counselling

Therapeutic counselling aims to help people to cope with the consequences of infertility and treatment, and to help them to resolve the problems they may encounter. It may include helping people to adjust their expectations and to accept their situations. It would usually involve two or more sessions of counselling.

1.4 Counselling to help with decision making on whether to discontinue treatment

Those participating in treatment may need help in making the decision to discontinue treatment.

Section 2 Number of counselling sessions per couple/individual**2.1 First time counselling**

In addition to recording the type of counselling provided, information is also required on the number of couples/individuals who attended counselling for the first time. When recording first time interviews, ensure that only the first interview for any couple is recorded. This means that if one member of a couple is seen, that is the first interview. If the other partner is seen subsequently or both partners are seen together, that is the second interview for that couple.

2.2 People having more than one session of counselling

Information is also required on people who have more than one session of counselling. Such information includes, whether they self-referred or were referred from the clinic or other service; the type of counselling they requested; the average number of sessions per individual or couple; whether the person paid for the service or whether it was covered by fees paid to the clinic; and other information provided by the counsellor.

Section 3 Other counselling activities

Please list any other activities carried out by counsellors at the clinics. These could include: group counselling sessions; group information sessions; staff consultation and education; seminar presentations; professional development; etc.

The attached sheet should be completed and returned to the Reproductive Technology Council at the end of each financial year.

COUNSELLING REPORTING FORM**Section 1 Total number of counselling sessions, identifying the main type of counselling**

This section relates to *all counselling sessions* throughout the year, separating the sessions given to couples and those given to individuals. When calculating 'total # sessions' choose the *main* type of counselling provided in that session (ie. do not record *one* counselling session more than once on **Section 1** of the form). Counselling has been divided into: providing information; giving support; therapeutic services; and helping people to decide to discontinue treatment.

1.1 Information Counselling

People seeking treatment	Couples total # sessions	Individuals total # sessions
IVF /GIFT		
Own Gametes	_____	_____
Donor Gametes/Embryos	_____	_____
ICSI		
Own Gametes	_____	_____
Donor Gametes	_____	_____
AI/UI		
Own Gametes	_____	_____
Donor Gametes	_____	_____
People donating	Couples total # sessions	Individuals total # sessions
Known donor		
Egg Donor	_____	_____
Sperm Donor	_____	_____
Embryo donor	_____	_____
Unknown donor		
Egg Donor	_____	_____
Sperm Donor	_____	_____
Embryo donor	_____	_____

1.2 Support Counselling

People receiving treatment and donors	Couples total # sessions	Individuals total # sessions
Own gametes/embryos	_____	_____
Recipient of donated gametes/embryos	_____	_____
Donor of gametes/embryos	_____	_____
Other	_____	_____

1.3 Therapeutic Counselling

People receiving treatment and donors	Couples total # sessions	Individuals total # sessions
Own gametes/embryos	_____	_____
Recipient of donated gametes/embryos	_____	_____
Donor of gametes/embryos	_____	_____
Other	_____	_____

1.4 Counselling for decision whether to discontinue treatment

People receiving treatment	Couples total # sessions	Individuals total # sessions
	_____	_____

Section 2 Number of counselling sessions per couple/individual

The first part of section 2 gives information on the number of people who attended one only session of counselling during the year. The second part gives information on people who attended more than one session of counselling in the year.

2.1 # Couples and/or individuals attending one counselling session

When recording first counselling sessions, ensure that only the **first** session for any couple is recorded. If one member is seen first and subsequently the second member is seen or the couple is seen together, the latter session is the second session.

Information counselling _____

Support counselling _____

Therapeutic counselling _____

Other _____

2.2 # Couples and/or individuals attending more than one counselling session

(Exclude details of the first counselling session)

Average number of sessions per couple or individual _____

Reason for presenting

Seeking information _____

Seeking support _____

Seeking help in dealing with a matter relating to infertility and its treatment _____

Seeking help with a personal matter unrelated to infertility _____

Seeking help to manage a crisis _____

Other _____

Referral source

Self referred _____

Referred from clinic _____

Other referral source _____

Location of counselling

At the clinic _____

At another location _____

Method of Payment

Payment by participant _____

Payment by clinic _____

Other method of payment _____

Other information about couples and individuals attending more than one session of counselling

Section 3 Other counselling activities

Please record other activities completed by counsellors and their frequency. These activities could include group counselling sessions, group information sessions, staff consultation, staff training, presenting seminars, professional development, etc.

SCHEDULE 4—COUNSELLING

PART 1 APPROVED COUNSELLORS

PART 2 PSYCHO-SOCIAL PREPARATION FOR PARTICIPANTS PRIOR TO KNOWN DONATION

PART 1—APPROVED COUNSELLORS

The Council has established the following criteria for the recognition of suitably trained and qualified counsellors as 'approved counsellors' for the purposes of the Act.

An applicant must be able to demonstrate—

- appropriate university recognised training and qualifications in counselling theory and technique, involving counselling as an integral and recognisable part of that training;
- substantial and satisfactory supervised, post-training counselling experience in an applied setting utilising therapeutic skills; and
- reasonable knowledge of life span issues associated with infertility and psychosocial issues in infertility treatment.

In addition to being approved by the Council an applicant must be eligible for full membership of the Australian and New Zealand Infertility Counsellors' Association (ANZICA) and it is desirable that she/he has broad clinical experience that includes assessment and diagnostic skills.

1.1 Criteria for approval of counsellors

i) **Appropriate training and qualifications in counselling theory and technique, as indicated by substantial academic qualifications, recognised by a university, involving counselling as an integral and recognisable part of that training**

Applicants must produce documentary evidence that they have completed a university recognised counselling course.

These courses must include both—

- 1 counselling theory undertaken in a university recognised course, covering at least two theoretical counselling approaches; and
- 2 counselling practice comprising substantial supervised course work.

ii) **Substantial and satisfactory supervised, post-training counselling experience in an applied setting utilising therapeutic skills**

Applicants must provide detailed evidence of satisfactory therapeutic case work which follows their training in counselling, to show that they have been supervised for approximately one hour per week over two years. This experience may be in more than one area, but the applicant must outline their therapeutic clinical experience, the way the supervision was conducted and name their supervisor as one of their referees. The supervisor must be a counsellor who has a recognised formal qualification and at least two years' postgraduate training supervision and three years' post training experience.

Specific areas of post training clinical and therapeutic counselling experience that may be relevant include—

- relationship issues; grief and loss counselling; problem solving/decision making; stress management;
- crisis counselling; sexuality counselling; life options counselling; pre-donation counselling; pre-recipient counselling; known donation family counselling; psychotherapy for conditions related to medical treatment (eg needle phobias); treatment outcome counselling.

Note: It is not envisaged that counsellors will possess *all* these skills. Expertise in the above areas could be developed as part of clinical practice in this field.

iii) **Reasonable knowledge of life span issues associated with infertility and psychosocial issues in infertility treatment**

Applicants must be able to provide evidence of reasonable knowledge of life span issues associated with infertility and psychosocial issues in infertility treatment. These include a reasonable understanding of aspects of the Human Reproductive Technology Act that may have counselling implications. Applicants must provide details of the method by which this knowledge has been obtained, eg course work; work experience; personal experience. Work or personal experience must be substantial. One of the referees named should be able to report on the applicant's knowledge of these issues. As currently there are no specific training programs in this area, the Council encourages and endorses special training programs on these infertility issues for time to time. An applicant not able to meet this criterion may be eligible for Conditional Approval.

Note: Applicants who cannot demonstrate that they fit the criteria as listed above, but who believe they can demonstrate by other means that they meet the criteria, may apply, outlining their qualifications and experience.

Applicants from regional and/or rural Western Australia may be recognised as 'approved counsellors' when *all* conditions are not met. This is to ensure that participants of infertility treatment from regional and rural areas are not deprived of counselling. However, as far as possible, appropriately qualified and experienced counsellors are sought to provide this type of counselling.

1.2 Applying for recognition as an 'approved counsellor'

An application from a counsellor for recognition by the Council should—

- be made in writing to the Reproductive Technology Council, documenting claims to meeting the criteria;
- include evidence of attendance at least 4 Reproductive Technology Council, endorsed ART events such as RTC Seminars, Approved Counsellors' quarterly meetings, FSA meetings, ANZICA workshops;
- include the names and addresses of three persons able to provide professional references to support the application, at least two of whom should be able to make reference to the counselling experience, abilities or relevant expertise that are to be demonstrated in support of the applicant's claim to meet the essential criteria; and
- include professional addresses and contact details such as telephone and fax numbers, and preferred address for general correspondence.

1.3 Approval Process

Applications will be referred by the Council for the consideration of the Counselling Committee and that Committee's recommendations regarding approval will be submitted to the Council for ratification.

1.4 Conditions of approval

Conditions may be placed on any approval, for example, requiring ongoing training, monitoring and supervision. During this period of *conditional approval*, the counsellor's name will not be published on the list of 'approved counsellors'.

An '*approved clinic counsellor*' in a licensed practice is required to submit a report to the Council by 31 July each year, detailing all counselling sessions offered in the practice during the previous financial year in relation to the requirements of the Act, in accordance with Part 5 of Schedule 3.

1.5 Conditional approval

Conditional approval may be granted in special circumstances, subject to conditions appropriate to the situation.

The Council may grant conditional approval to an applicant, for a period specified in the approval, on the demonstration of what the Council believes to be appropriate training and clinical experience in counselling. During the period of conditional approval such conditions as are set by the Council, on the advice of the Counselling Committee, must be met. These conditions may vary according to the areas of professional experience of the counsellor. This type of conditional approval may apply, for example, when an experienced counsellor is commencing practice in the field of infertility, based on an understanding to gain knowledge of infertility issues.

During the period of conditional approval, the counsellor's name will not be published on the list of 'approved counsellors' that is circulated by the Council and updated from time to time.

1.6 Term of approval

Approval will normally be recommended for a three-year term. An application to apply for renewal of approval should be made three months prior to the expiration of the current approval.

1.7 Application for renewal of approval

An application for renewal of approval should be made to the Council in writing. Each counsellor will be responsible for re-applying for recognition, and failure of the Council to remind the counsellor that their term of appointment is expiring will not be cause for a complaint, although the Council will usually issue this reminder.

When considering an application for re-recognition, the Council will consider evidence of the counsellor's ongoing education and involvement in the area of infertility during the term of recognition.

Evidence that should be provided to demonstrate that this has been adequate may include details of the counsellor's infertility case load and information indicating how relevant knowledge and skills have been developed during the term of recognition.

For example, suitable evidence may include—

- attendance at the Fertility Society of Australia's Annual Scientific Meeting, or similar conferences or meetings;
- attendance and/or participation in council workshops and seminars;
- active membership of relevant professional groups such as a group of clinic counsellors;
- active membership of a relevant patient support group; and
- participation in formal education in the area.

1.8 Availability of Approved Counsellors Employed by Licensed Clinics

Approved Counsellors should be integral members of the clinic team employed on a permanent basis by the clinics.

Approved Counsellors are to be available for scheduled counselling appointments with participants, as well as for other activities, such as follow up of participants with failed cycles and miscarriages, telephone counselling, support groups, debriefing and professional development for clinic staff.

**PART 2—PSYCHO-SOCIAL PREPARATION FOR PARTICIPANTS
PRIOR TO KNOWN DONATION**

The following counselling/psycho-social preparation is required to be provided prior to any artificial fertilisation procedure where a donor is known to the recipients, in accordance with the requirements in Direction 5.8.

- Counselling must be provided by an approved counsellor;
- Counselling should preferably be provided before the medical assessment of the participants;
- Information that has been approved by the Council in accordance with the Directions should be provided to each participant;
- Initial counselling should include a minimum of three hours counselling in three individual sessions during which the recipient (and spouse or de-facto spouse, if any) and donor (and spouse or de-facto spouse, if any) should be seen separately and then together;
- A six month cooling off period should be allowed following the completion of initial counselling before the donated material is used in an artificial fertilisation procedure;
- At the end of the cooling off period each participant should have further contact with the 'approved counsellor' to ensure her/his continued willingness to proceed;
- An exit interview with an 'approved counsellor' must be provided for participants who are not proceeding with the program;
- All counselling should be face to face unless this is very difficult to arrange. If face to face counselling cannot be arranged the approved counsellor may conduct the counselling by phone or video-link;
- Counselling of a person who is not resident in WA may be provided by a interstate or overseas counsellor who is a member of the Australian and New Zealand Infertility Counsellors Association (ANZICA) (or equivalent);
- The costs of counselling would generally be borne by recipients.

SCHEDULE 5—PROTOCOL MANUALS**PART 1 REQUIREMENTS FOR PROTOCOL MANUALS****PART 2 CRITERIA FOR DECIDING IF A PROCEDURE IS ROUTINE****PART 1—REQUIREMENTS FOR PROTOCOL MANUALS**

Clinic protocol manuals must comply with Reproductive Technology Accreditation Committee/ National Association of Testing Authorities (RTAC/NATA) standards generally and include all details set out in this Schedule.

All relevant routine laboratory procedures set out in section 4 of this Part require the approval of Council.

Direction 9.3 sets out the processes to be adopted by licensees when changes or additions to relevant procedures in the clinics are contemplated.

All changes to relevant protocols, patient information and consent forms must be recorded in the clinic's protocol manual, permanently annotated with date and version. All changes to procedures are to be notified at least at the time of annual reporting.

Where relevant the protocol manual should refer to appropriate sections of the Act and directions and use cross-referencing to other sections of the manual.

1. Protocols relating to Management and Staffing

- 1.1 Protocols setting out the requirements to notify Commissioner of Health of changes in circumstances or details of the licensee to operations at the clinic should be set out clearly and complied with.
- 1.2 Organisational charts and JDFs should set out relationships and responsibilities for all staff. JDFs should be included for the person responsible, the medical director; other medical staff; nursing staff; laboratory manager; embryologists; clinic counsellor; etc as required by RTAC.
- 1.3 Protocol establishing a program for regular staff meetings and the keeping of records from those meetings showing dates; attendance; matters discussed.
- 1.4 A program for staff training and keeping of records from these training programs showing dates; attendance; matters covered.
- 1.5 Protocols for regular QA of laboratory procedures and record keeping from these.

2. Details of Processes for Ensuring Informed Consent of all Participants

- 2.1 Information sheets for patients that provide information about all treatments and procedures that are subject to the Act (all artificial fertilisation procedures, storage of gametes and embryos and all other uses of gametes and embryos), with appropriate date, version and authorisation. Where relevant these should be written in accordance with and refer to the Directions.
- 2.2 Consent forms relevant to treatments and procedures as above, with appropriate date, version and authorisation.
- 2.3 Details of the manner in which directions with regard to counselling are to be complied with.

3. Details of Clinical Protocols

- 3.1 A JDF for the Medical Director, providing evidence that they meet RTAC standards.
- 3.2 A protocol for training and oversight of other clinicians by the Medical Director.
- 3.3 Protocols for medical practitioners, referring them to matters elsewhere in the Protocol Manual that they are explicitly responsible for under the Act, for example relating to—
 - Consents, information giving and counselling generally;
 - The responsibility of medical practitioner for assessment of eligibility and keeping of records about this; treatment details and outcomes;
 - The requirement for a six month cooling off for known donor, fresh oocytes;
 - The minimum age for donation;
 - The limit to repeated ovarian stimulation;
 - The prohibition on posthumous use of gametes;
 - Protocols and limitations on import and export of donated material;
 - The limitation on export of embryos for purposes that would be against the law in WA.
- 3.4 Other clinical protocols of interest—
 - What medication protocols are used for Flare Up, Down Regulation etc.;
 - What criteria are used to determine when cycles are to be cancelled prior to OPU to prevent OHSS development;
 - What criteria are used to determine when all embryos will be frozen to prevent OHSS;
 - What criteria are used to determine when cycles are to be cancelled as not enough follicles are developing.

4. Detailed Laboratory Protocols

- 4.1 Protocols detailing all procedures relating to the collection and use of gametes and embryos. These protocols should include—
- Grading oocytes;
 - Selecting oocytes for use/discarding;
 - Grading embryos;
 - Criteria for embryos to be transferred;
 - Selecting embryos for freezing;
 - Classifying survival of thawed embryos, and determining which are suitable for transfer.
- 4.2 Protocols relating to data collection and reporting, including—
- Protocols for maintenance of clinic Database/reporting to RTAC/RT Register and Annual Reporting requirements;
 - Protocols for database of gamete and embryo storage/ for managing embryo extensions.
- 4.3 Protocols relating to donor screening and selection and use of donor reproductive material, including—
- Protocols for screening of donors/donor consent;
 - Protocols for export donor/import donor;
 - Protocols to ensure the five family limit.
- 4.4 Protocols for processes for introducing changes to protocols into the clinic/Reporting of changes.
- 4.5 Protocols for all approved innovative procedures: reporting requirements etc special conditions for each case.
- 4.6 Protocols any approved research procedure involving gametes, embryos or participants, ethics and Council approval, information about reporting requirements.

PART 2—CRITERIA FOR DECIDING IF A PROCEDURE IS ROUTINE

For a procedure to be considered routine documentation should be able to be provided to the Council (on request) showing that the procedure adopted—

- complies with any standards set by any relevant professional body and, if relevant, standards set in the NHMRC's National Statement on Ethical Conduct in Research Involving Humans;
 - has not been rejected by a relevant Human Research Ethics Committee;
 - is used in other reputable, nationally or internationally recognised clinics;
 - is reported in international peer-reviewed literature, indicating safe and successful outcome, based on good research;
 - is expected to be, or is currently, successful in the local clinic (eg details of results or relevant staff training undertaken); and
 - is considered a necessary element of the routine practice in the clinic.
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