WESTERN AUSTRALIAN GOVERNMENT gazette
ISSN 1448-949X (print) ISSN 2204-4264 (online)
PRINT POST APPROVED PP665002/00041

PERTH, WEDNESDAY, 23 JUNE 2021 No. 112 SPECIAL

PUBLISHED BY AUTHORITY GEOFF O. LAWN, GOVERNMENT PRINTER

SURROGACY ACT 2008

SURROGACY AMENDMENT REGULATIONS 2021

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

HUMAN REPRODUCTIVE TECHNOLOGY DIRECTIONS 2021

Surrogacy Act 2008

Surrogacy Amendment Regulations 2021

SL 2021/96

Made by the Governor in Executive Council.

1. Citation

These regulations are the *Surrogacy Amendment Regulations 2021*.

2. Commencement

These regulations come into operation as follows —

(a) regulations 1 and 2 — on the day on which these regulations are published in the *Gazette*;

(b) the rest of the regulations — on the day after that day.

3. Regulations amended

These regulations amend the *Surrogacy Regulations 2009*.

4. Regulation 3 replaced

Delete regulation 3 and insert:

3. Term used: counsellor

In these regulations —

counsellor means a person who is eligible for full membership of the Australian and New Zealand Infertility Counsellors Association.

Surrogacy Amendment Regulations 2021

r. 5

5. Regulation 4 amended

(1) In regulation 4(1) delete "an approved counsellor" and insert:

a counsellor

(2) In regulation 4(2) and (3) delete "approved".

6. Regulation 6 amended

In regulation 6 delete "an approved counsellor" and insert:

a counsellor

N. HAGLEY, Clerk of the Executive Council.

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

HUMAN REPRODUCTIVE TECHNOLOGY DIRECTIONS 2021

Given by the Chief Executive Officer (CEO) 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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HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

HUMAN REPRODUCTIVE TECHNOLOGY DIRECTIONS 2021

INTRODUCTION

These directions are given by the CEO in accordance with section 31 of the *Human Reproductive Technology Act 1991* (the Act). These directions may be referred to as the Human Reproductive Technology Directions 2021.

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 / partner's sperm;

"ANZICA" means the Australian and New Zealand Infertility Counsellors Association;

"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;

"**Commissioner of Health**" means the Commissioner of Health referred to in section 6(1)(a) of the *Health Legislation Administration Act 1984* as in force before commencement of the *Machinery of Government (Miscellaneous Amendments) Act 2006*.

"Counsellor" means a person who is eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA);

"Data Submission Specifications" means the *Reproductive Technology Registers Data Submissions Specifications* published by the Department of Health on its website as amended from time to time;

"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 Fallopian 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 CEO 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;

"Serious adverse event" has the meaning given in the definitions of the Code of Practice for Assisted Reproductive Technology Units published by RTAC (Issued October 1987 and revised October 2017) as amended from time to time;

"Serious notifiable adverse event" has the meaning given in the definitions of the Code of Practice for Assisted Reproductive Technology Units published by RTAC (Issued October 1987 and revised October 2017) as amended from time to time;

"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.

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

Copies of the Act may be obtained from—

https://www.legislation.wa.gov.au

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 a 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 CEO 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 requirements**

All licensees and exempt practitioners must submit the following data and information in accordance with the Data Submission Specifications—

(a) data relating to reproductive technology treatments carried out by the licensee for donor insemination, oocyte pickup, storage or fertilisation and embryo storage or transfer including information—

(i) the licensee is required to submit to the Australian and New Zealand Assisted Reproduction Database (ANZARD) for use by the Fertility Society of Australia (FSA); and

(ii) that describes the donor of any gametes or embryos used in treatments by the licensee.

(b) identifying particulars of participants, surrogates, and donors of gametes and embryos;

(c) demographic information that is non-identifying about all donors of gametes and embryos; and

(d) identifying and other particulars of live births from donated material exported from Western Australia by the licensee, including information about the recipient of the donated material.

***2.6 Restriction on provision of donated 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.

***2.7 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 required by 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.

***2.8 Transfer of responsibility to report to the CEO**

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.

***2.9 Exceptions to the requirement to report donor identity**

A licensee is not required to supply to the CEO 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.

***2.10 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.

2.11 Annual reporting

Licensees and exempt practitioners must submit an annual report to the CEO by 31 July each year relating to the previous financial year. The annual report must include the information set out in Schedule 2.

2.12 Notification of change in circumstances or details of licensee

A practice or storage licensee must notify the CEO within 48 hours and in accordance with the method of required notification in direction 2.16 if any of the following events occur.

2.12.1 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 2.12.1 (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;

2.12.2 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;

2.12.3 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;

2.12.4 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;

2.12.5 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;

2.12.6 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;

2.12.7 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;

2.12.8 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.

2.13 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.

2.14 Notification of serious adverse events

The licensee must—

(a) notify the CEO of any serious adverse event or serious notifiable adverse event within 7 days of its occurrence or within 7 days of becoming aware of its occurrence; and

(b) provide the CEO with information about any investigations undertaken by the licensee into an event notified under direction 2.14 (a), and any corrective actions taken by the licensee within 6 weeks of the occurrence of the serious adverse event or serious notifiable adverse event.

2.15 Copy of annual RTAC audit report to be provided to the CEO

The licensee must provide the CEO with the following reports within 7 days of their receipt—

(a) a copy of its annual audit report on its compliance with the RTAC Code of Practice received from a certifying body of the RTAC; and

(b) if there are non-compliance issues identified in the annual audit report, a copy of any stand-alone reports of any follow-up on-site audits received from a certifying body of the RTAC once the non-conformities have been closed out by the certifying body.

2.16 Method of required notification

Notifications and reports called for by directions 2.11, 2.12, 2.13, 2.14, 2.15 and 9.3(f) must—

(a) be in writing and must be given only by email or registered post,

addressed to—

Executive Officer
Western Australian Reproductive Technology Council
VIA the Licensing and Accreditation Regulatory Unit
Department of Health
189 Royal Street, East Perth WESTERN AUSTRALIA 6004
Email: LARUReception@health.wa.gov.au

OR such other address as may be provided;

and

(b) contain sufficient information to enable the CEO 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.

2.17 Further particulars

If the CEO 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 2.12.1-8 have occurred, the licensee must, within any time limit specified, provide the CEO 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 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.

***3.2 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.

3.3 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.

3.4 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.

3.5 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.

3.6 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.

3.7 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.

3.8 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.

3.9 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, 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 CEO 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 a 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, 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, 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 l 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 a counsellor

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

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

The licensee must ensure that the 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 counsellor

The licensee must ensure that the overall cost of treatment includes the cost of at least one consultation with a 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 a 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 sperm 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, that—

(a) encourages the donor to seek assistance with decision making and counselling in preparation for donation;

(b) provides information about the availability of counsellors to assist with decision making, including a list of 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, that—

(a) strongly encourages the donor to seek assistance with decision making and counselling from a counsellor and provides a list of 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 Schedule 3 or such other psycho-social preparation as has been approved by the Council.

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 5 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 Records of period of storage of gametes, 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.

6.9 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.

6.10 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 3 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 3 is provided to a person who wishes to seek an extension to the authorised storage period.

6.11 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 for approval to extend the storage of an excess ART embryos that have been donated for a use requiring an NHMRC licence.

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

The licensee must complete a Form 4 application for approval to extend the storage period of an excess ART embryo that has been donated for research and provide the application to 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 HIV 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 donated gametes, embryos or eggs 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 3 months has elapsed between the donor and recipient completing psychosocial 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 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 4 is kept and maintained.

9.2 Approval of routine laboratory and clinical procedures

(a) The licensee must ensure that all routine laboratory and clinical procedures to be followed are set out in its protocol manual and must submit the protocol manual to the Council for approval.

(b) Routine laboratory procedures and clinical procedures are procedures that meet the criteria outlined in Part 2 of Schedule 4. The licensee must provide the Council with evidence demonstrating that a procedure meets the criteria outlined in Part 2 of Schedule 4 when requested by the Council.

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 using Form 1 in Schedule 1;

(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 2.16.

9.4 Approval for innovative procedures

The licensee must ensure that each laboratory or clinical 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 4.

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 laboratory or clinical 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 30 November 2004

Directions given by the Commissioner of Health under the *Human Reproductive Technology Act 1991* and published in the *Western Australian Government Gazette* on 30 November 2004 are revoked.

SCHEDULE 1—FORMS

FORM 1

APPLICATION FORM FOR SPECIFIC APPROVAL OF AN INNOVATIVE PROCEDURE

DIRECTIONS 9.4 AND 9.5

Name of Licensee: .....
.....
Licence supervisor: (Full name) .....
Address: .....
.....
.....
Tel: .....
Fax: .....
Human Research Ethics Committee: ..... \.....
Chairperson (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: ..... (Chairperson, 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 specify—

(1) Whether HREC approval has been sought and, if so, provide any comments on the proposal by the relevant HREC.

(2) With 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) With 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
Licensing and Accreditation Regulatory Unit
Department of Health
189 Royal Street, East Perth WESTERN AUSTRALIA 6004
Email: LARUReception@health.wa.gov.au

FORM 2

APPLICATION FORM FOR SPECIFIC APPROVAL OF RESEARCH
HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991
DIRECTIONS 9.6 AND 9.7

Name of Licensee: .....
.....
Licence supervisor: (Full name) .....
Address: .....
.....
.....
Tel: .....
Fax: .....
Human Research Ethics Committee: ..... \.....
Chairperson (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—

(i) provide the Council with a progress report on the project annually, at the time of annual reporting;

(ii) notify the Council if the research is terminated, with a full report of the findings; and

(iii) 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: ..... (Chairperson, Reproductive Technology Council)

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

Before completing please read Directions 9.6 and 9.7

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 Commonwealth Research Involving Human Embryos Act 2002.

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) With 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, give 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 Commonwealth *Research Involving Human Embryos Act 2002).*

(6) Full details of the proposal.

(7) Supporting Documentation, references.

Please return to—

The Executive Officer
The WA Reproductive Technology Council
VIA the Licensing and Accreditation Regulatory Unit
Department of Health
189 Royal Street, East Perth WESTERN AUSTRALIA 6004
Email: LARUReception@health.wa.gov.au

CONFIDENTIAL

FORM 3: APPLICATION FOR EXTENSION OF FROZEN EMBRYO STORAGE PERIOD FOR USE IN IVF PROCEDURE

Direction 6.10

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 email: embryo.storage@health.wa.gov.au

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 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

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 if applicable:

Female ☐☐☐☐☐☐☐☐ **Partner** (if any) ☐☐☐☐☐☐☐☐

Health Department use only: **Application Number** ☐ - ☐☐☐☐ **Code** ☐☐

Date of Expiry of Extended Storage Period ☐☐ day ☐☐ month ☐☐ year

Chairperson, RTC _____

CONFIDENTIAL

PART B

Eligible Participant(s) to complete:

Date of Application ☐☐ day ☐☐ month ☐☐ year

Eligible Participant name:	**Female**	**Partner** (if any)
	Family name _____	**Family name** _____
	Given name _____	**Given name** _____
Signature:	_____	_____
Address:	_____	
Postcode:	☐☐☐☐	**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 4: APPLICATION FOR EXTENSION OF PERMITTED STORAGE PERIOD WHERE EXCESS ART EMBRYOS HAVE BEEN DONATED FOR A USE REQUIRING A LICENCE FROM THE NHMRC

Direction 6.12

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
  embryo.storage@health.wa.gov.au

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

Licensee ☐☐☐

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4. Treatment cycle details:

Participant ID Code ☐☐☐☐☐☐☐☐ **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

Female DOB: ☐☐ day ☐☐ month ☐☐ year **Partner** ☐☐ 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

Chairperson, RTC _____

_____

FORM 5

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 provide 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 the licensee with recipient identifying information as required by the licensee to meet its obligations under the *Human Reproductive Technology Act 1991*;

3. To provide the recipient and their spouse/partner with all relevant information, especially regarding the Registers which have been established under section 45 of the Act, 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—ANNUAL REPORTING REQUIREMENTS

Direction 2.11 requires all licensees and exempt practitioners to submit an annual report to the CEO. The annual report for each financial year ending 30 June is required to be submitted by 31 July of the following financial year. The information required is set out in this Schedule.

The annual report for each licensee or exempt practitioner must state the practice licence or exemption number and include the information set out in this Schedule.

1. Intra uterine insemination procedures

Practice licence or exemption number .....

Record the number of pregnancy outcomes for each of the intra uterine insemination (IUI) procedures performed indicating use of ovarian stimulation and/or donated gametes in the table below. All sections must be completed, with a 'nil' return for those sections that are not applicable.

IUI Procedures

	Ovarian Stimulation			
	Yes		No	
	Donor	Partner	Donor	Partner
Not pregnant				
Singleton*				
Twins*				
Higher order*				
Unknown				
Total				

*Record the number clinical pregnancies that reached 8 weeks gestation

2. In vitro fertilisation treatments

Practice licence number..... **Storage licence number**.....

Record the number of participants/couples treated and the number of specified vitro fertilisation (IVF) treatment cycles for the fresh and thawed IVF treatments in the table below. Include public patients treated. All sections must be completed, with a 'nil' return for those sections that are not applicable.

Fresh embryo transfer cycles	n
Women treated	
Treatment cycles begun	
Cycles with oocyte retrieval	
Cycles with embryo transfer	
Cycles using donor sperm	
Cycles using donor oocytes	
Cycles using donor embryos	
Cycles where embryos were frozen	
Cycles from which oocytes were donated	
Cycles with intracytoplasmic sperm injection (ICSI)	
Cycles with Mixed IVF/ICSI	

Frozen embryo transfer (FET) cycles	n
Women treated	
Treatment cycles begun	
Cycles with embryo transfer	
Cycles using donor sperm	
Cycles using donor oocytes	
Cycles using donor embryos	

3 Information on 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;

(b) Female identification number (FID);

the number of follicles over 12mm noted at any ultrasound; and

any additional evidence of ascites (clinical or ultrasound) or an abnormal haematocrit).

(c) 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 number).

(d) 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 male identification number r, treatment cycle ID number, 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) Record the treatment details for participants referred from the King Edward Memorial Hospital infertility clinic in the table below.

Public patient treatments	n
Women treated	
Treatment cycles initiated	
Cycles with oocyte retrieval	
Fresh cycles with IVF	
Fresh cycles with ICSI fertilisation	
Cycles with fresh embryo transfer	
Cycles with thawed embryo transfer	
Cycles with IUI	
Cycles using donated gametes or embryos	

4 Information about any research or innovative practice

(i) Summary information about any research, 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.

5 Information about complaints received

(i) Summary information about any complaint formally laid by a participant, including the nature of the complaint and any actions taken be the licensee.

6 Gamete and embryo donation

Provide the number of new sperm and oocyte donors; (known and unknown) with breakdown by donors age.

Provide the number of new embryo donors.

Only report information about donations that became available for treatment (cleared quarantine) in the reporting year. Do not include cryopreserved donor gametes imported into the clinic.

7. Embryo storage

Provide embryo storage data in the table below. All sections must be completed with a 'nil' return for those sections that are not applicable.

Embryo storage	n	
	In	Out
At 30 June previous year		-
Following IVF by licensee		-
From other WA clinics		-
From clinics outside WA		-
Thawed/ warmed for treatment or a procedure*	-	
Allowed to succumb	-	
Sent to other WA clinics	-	
Sent to clinics outside WA	-	
Removed for research	-	
Total		
Total embryos in storage at 30 June this reporting year		

*Include embryos that failed to thaw/warm.

8. Counselling information

8.1 Counselling accessed by participants

Record the type and frequency of counselling sessions attended by an individual/couple. Individuals/ couples should be reported as one unit for the purpose of this table.

Record if the individual/couple attended one session only or more than one session. Do not double count individual/couple in both columns.

If more than one type of counselling was undertaken in a session, then record the session under the main type of counselling provided in the table below.

All sections must be completed with a 'nil' return for those sections that are not applicable.

Table 7: Counselling accessed by participants

Type of counselling	One session only	More than one session
Information counselling		
own gametes/ embryos		
recipient of donated gametes/ embryos		
donor of gametes/ embryos		
surrogacy related		
Total		
Support counselling		
own gametes/ embryos		
recipient of donated gametes/embryos		
donor of gametes/ embryos		
surrogacy related		
Total		
Therapeutic/ other counselling		
own gametes/ embryos		
recipient of donated gametes/ embryos		
donor of gametes/ embryos		
surrogacy related		
Total		

8.2 Number of counselling sessions

This section is to record the number of counselling sessions provided and the proportion related to donor conception treatments.

Total number of counselling sessions accessed .....

Number of donor/recipient related sessions accessed .....

SCHEDULE 3—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 a counsellor as defined by these Directions;
- Counselling should preferably be provided before the medical assessment of the participants;
- 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 three 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 counsellor to ensure her/his continued willingness to proceed;
- An exit interview with a counsellor must be provided for participants who are not proceeding with the program;
- If face to face counselling cannot be arranged the counsellor may conduct the counselling by telephone or audiovisual communication;
- Counselling of a person who is not resident in WA may be provided by an interstate or overseas counsellor who meets the definition of counsellor in these Directions;
- The costs of counselling will generally be borne by recipients.

SCHEDULE 4—PROTOCOL MANUALS

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. Compliance with this Schedule ensures that all protocols, including the relevant routine laboratory procedures set out in section 4 of this Part, are approved by 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 the CEO 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 job description forms (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 quality assurance 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 three month cooling off for known donation
- The minimum age for donation;
- 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 oocyte pick up (OPU) to prevent ovarian hyperstimulation syndrome (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/Department of Health 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 A ROUTINE LABORATORY OR CLINICAL PROCEDURE

For a procedure to be considered a routine laboratory or clinical procedure it must—

- comply 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;
- not have been rejected by a relevant Human Research Ethics Committee;
- be used in other reputable, nationally or internationally recognised clinics;
- be reported in international peer reviewed literature, indicating safe and successful outcome, based on good research;
- be expected to be, or is currently, successful in the local clinic (eg details of results or relevant staff training undertaken); and
- be considered a necessary element of the routine practice in the clinic.