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DRAFT GUIDELINES

TO ASSIST IN COMPLIANCE WITH DIRECTIONS ISSUED BY THE COMMISSIONER OF HEALTH UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991, ON THE ADVICE OF THE WA REPRODUCTIVE TECHNOLOGY COUNCIL

10666/3/93—1350

HUMAN REPRODUCTIVE TECHNOLOGY ACT

DRAFT GUIDELINES

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These draft guidelines are intended to assist licensees in following the directions given by the Commissioner, and to explain some aspects of the Act itself. The intention of the Reproductive Technology Council in making this document available is that it should serve a similar function to guidelines that will make up Part II of the Code of Practice, when this is laid before Parliament as specified in sections 15 and 16 of the Act.

*** Throughout the DIRECTIONS and Guidelines any reference to an embryo includes a reference to an egg in the process of fertilisation.**

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SECTION 1: LICENSING

1.1 What are the licensing procedures?

i) In the initial phase, prior to proclamation of the Act, potential applicants are notified, personally or through general publicity, of the need to apply to the Commissioner for Licences or Exemptions; and

after proclamation of the Act any licensee wishing to apply for a renewal of a current Licence must apply no later than three months prior to expiry of the current licence and any new applicant must apply at least three months prior to their intended time of beginning to practice under the Act;

ii) the applicant approaches the Commissioner, requesting application forms and relevant information;

iii) the Commissioner sends out application forms, including application forms for approval for any research or for any diagnostic testing of embryos to be carried out or facilitated by the licensee and requiring Council approval, as well as supporting material on requirements for licensing, the Code or directions;

iv) on receipt of an application with signed declarations and documentation and with the prescribed fee payable to the Commissioner of Health, the Commissioner should inform the Council and seek their advice as to suitability of the applicant;

v) Council makes a recommendation to the Commissioner as to the suitability of the applicant, based on **Reproductive Technology Accreditation Committee (RTAC) and National Association of Testing Authorities (NATA) accreditation;** and/or

any other investigation required by Council;

vi) the Commissioner sends out the licence or notice of receipt of application for Exemption, although in the case of an Exemption this is not required by the Act, as this may be 'deemed to be issued' unless conditions are to apply; and

vii) the licence, licensee or exemption and required particulars are registered with the Commissioner.

1.2 What evidence of suitability of personnel is to be attached to applications and available on request at other times ?

As indicated on the relevant application form, the following evidence is required:

. copies of CV's, qualifications and references for all key staff indicated on the application form, including for any approved counsellor this appointment is required under the directions;

. indication by all these people as to whether they have ever applied for a licence for any relevant trade or profession, what the result of that application was, its current status and, if no longer in effect, why this is so;

. evidence, if relevant, of current NATA/RTAC accreditation or relevant correspondence;

. applications for/evidence of Reproductive Technology Council (RTC) approval for any research or embryo diagnostic testing; and

. a protocol manual, as described in Section 9 of the directions (research and diagnostic testing).

1.3 How will the Commissioner ascertain whether the required standards have been met for licensing?

Current RTAC/NATA accreditation and/or advice given to the Commissioner from investigations carried out by Council may be taken as evidence that these standards are being met. Council may arrange site visits to assess the suitability of applicants, the premises, the equipment or procedures.

1.4 The person responsible

The person responsible is defined by the Act and has a number of key responsibilities for activities carried out under the Licence or Exemption. The person responsible is named in the licence, and is important to the proper practice of reproductive technology, as well as to the attainment of the objects of the Act. This person must be in a position to discharge his or her statutory duties as set out in the Act, section 51(2), and any other duties specified in the relevant licence, the Code of Practice or any direction under the Act. The Act spells out in some detail what that person's responsibilities are, and what is the liability of the licensee for an act of an employee. [S.52]

Therefore the person responsible should attend on a regular basis at the premises to which the licence relates.

. Absences of the person responsible.

If the person responsible is expected not to be in a position to discharge the duties indicated because of a temporary absence, as on annual leave, that person must apply to the Commissioner for approval for such absence. Otherwise that person remains the person responsible. Any such approval may be granted on terms that the licensee appoint a person to discharge those duties, or that duty, as indicated in the Act [S.51].
If the newly appointed person responsible is not considered suitable, the Commissioner may fail to grant this approval.

1.5 What sort of complaints procedure should be in place for patients?

RTAC guidelines require each clinic to have a complaints procedure to be in place. Participants must be informed of this procedure, and that there are other standard routes for complaints about medical matters if this process fails. They should also be informed that they may contact the Reproductive Technology Council if necessary. Licensees will be asked to include in their Annual Report to the Commissioner a summary of complaints made through this formal complaints process.

1.6 Can a licence cover premises at different addresses?

There is no reason why a licence under the Act cannot cover premises at several addresses, even where these are not adjacent or even in the same neighbourhood. However, the premises to which the licence relates must all be specified in the licence, and the Commissioner may refuse to include premises under certain circumstances. For example, as section 51(1)(a) of the Act makes it clear that there must be one individual only responsible for each licence the Commissioner may refuse to include certain premises in the licence if not satisfied as to the capacity of the licensee to ensure adequate supervision of the separate premises, having regard to the number of separate premises or their distance from each other.

1.7 How will licensee compliance be monitored?

Review of licensee compliance will normally be carried out at 6 months, followed by further reviews at 2 and 3 1/2 years, as licences may be issued for 5 years. Officers required to carry this out must be authorized officers.

On the advice of Council the Commissioner may at other times give directions requiring reports relating to

specific matters of relevance to the administration of the Act

1.8 Powers and identification of authorized officers

Authorized officers are to be specifically appointed by the Commissioner of Health and must carry a certificate of identity that indicates their powers and functions. The Act [S.49,54] spells out their powers and duties.

1.9 Who may be exempt or excluded from the licensing requirement although carrying out artificial insemination ?

i) **Medical practitioners may apply for an Exemption from the licensing requirement to carry out artificial insemination. An application for this exemption must be made to the Commissioner of Health, in the prescribed format.**

ii) **Several other groups of persons who are not medical practitioners are excluded by regulation from any requirement for licensing or exemption for artificial insemination.**

These include those persons, **other than medical practitioners, such as nurses or spouses,** acting under the direction of a licensee or exempt practitioner, on the condition that they give a written undertaking to report the outcome of the use to the supplier of the semen.

1.10 Differing requirements for Storage Licences.

With regard to Storage Licences covering the storage of semen only, depending on whether or not the Storage licensee collects semen or simply stores it, and whether the semen is only for AIH or for donation, there are several basic differences in requirements for the licensees.

It is the Storage licensee who collects semen for donation who has the greater responsibilities, including reporting on outcomes of all the semen used to the Donor Register, and having a medical practitioner on staff to assess the donors according to RTAC guidelines, and reaching NATA standards in the laboratory. In addition the direction specify that the licensee must not continue to supply semen to an exempt practitioner or other person who has failed without good reason to report outcome of the use.

Other Storage licensees, who do not collect the donor semen they dispense or who collect and store semen only for AIH, have a responsibility to report on outcome of use of donor sperm to the Storage licensee who supplied them with the semen, and the person responsible for the licence is responsible to see that the standards of facilities and staffing are adequate for the activities carried on under the licence. There must be access to information and counselling, and the consent given to any procedure must comply with requirements of the Act, directions and Code.

There are no specific requirements under the Act relating to record keeping or reporting for AIH, beyond those dictated by good medical practice.

Where a licensee stores eggs or embryos there are specific requirements for reporting covered in section 2 of the directions or guidelines.

. **Practice issues in relation to donation**

1.11 What are the licensing requirements for artificial insemination?

If the artificial insemination procedure is to be carried out by a **medical practitioner** that practitioner requires an official **Exemption** from the Commissioner of Health to carry out the procedure. This practitioner is the person responsible for the exemption, with the responsibility to comply with relevant

sections of the Code of directions.

However, as stated in 1.9 above, others carrying out the procedure with semen provided by a Storage or Practice licensee or Exempt practitioner, such as a nurse or husband, are covered by regulations excluding them from the necessity to be licensed or exempt. The exclusion is conditional on their giving a written undertaking to report to the licensee about the outcome of the procedure, and the Storage licensee is required not to supply semen repeatedly to a person who fails to give this feedback.

1.12 No experimentation may be authorised under an Exemption

According to the Act, no experimentation may be authorised under an Exemption for artificial insemination. Therefore, if a person intends to carry out any research involving participants or on sperm, prior to its use in an artificial fertilisation procedure, they should apply for a Practice Licence and Council approval for the research.

SECTION 2: RECORD KEEPING, REPORTING ETC IN RELATION TO STORAGE AND DONATION

2.1 *What the Act says about records-keeping, in summary-*

i) Content

The Act states that records to be kept by licensees must contain the following information:

[S.44(1)(a)]

" ..in relation to gametes, eggs in the process of fertilisation and embryos kept and used by that licensee-

(i) identity and consent of donor of gametes, with date received;

(ii) biological parentage and date of fertilisation of any egg in the process of fertilisation (EPF) or embryo;

(iii) the place, period and method of collection and keeping of gametes, EPF and embryos;

(iv) the identity of any person to whom gametes, EPF or embryo was supplied, of every person for whom the gametes were, or an EPF or embryo was, used in an AF procedure, and if known the ultimate recipient;"

[S.44(1)(b]

"...in relation to all artificial fertilisation procedures carried out by or on behalf of the licensee showing-

(i) the identity of and full particulars as to the consent given by each participant;

(ii) the reasons why each participant was assessed as being an eligible person in respect of that procedure;

(iii) the nature of the procedure;

(iv) the identity of the individual who carried out that procedure; and

(v) where known-

(A) the outcome of the procedure;
(B) whether any children were born that appear to the person responsible to have been born as a result of the procedure; and
(C) sufficient particulars to identify each such child;

(c) all research relating to reproductive technology authorized or facilitated by or on behalf of that licensee; ..."

ii) Records about assessment of eligibility

Most importantly S.44(1)(b)(ii) requires there to be records kept as to why a person was considered eligible to be treated. This is particularly important for IVF procedures, as the Act is explicit in S.23 as to the eligibility criteria - especially marital status, infertility and age, but also consideration of the welfare of the couple and any child likely to be born.
The directions specify that the final responsibility as to assessment of eligibility rests with the medical practitioner, who must keep records that show the requirements are complied with.

iii) *The location of record keeping by licensees*

Section 44(3)(b) of the Act also gives power for the Commissioner to specify where these records are to be kept, however at this stage this also is to be left to the discretion of the licensee. S.44(5) also makes a statement about location, and refers to a power of the Commissioner to name a location for records that are to be held when a person ceases to be a licensee, so if this is anticipated the Commissioner should be contacted.

iv) *Method of storage and confidentiality of records kept by licensees*

Licensees should note that S.44 (3) (b) requires a licensee to keep the records secure and confidential, while S.49 establishes offences related to breaches of confidentiality which could relate to licensees retaining records under this Act.

v) *Offences in relation to record keeping and reporting*

The Act specifies a number of offences in relation to breaches of the confidentiality with which these records should be kept, and to the accuracy of any records or reports etc and the requirements to report or provide annual returns to the Commissioner in the prescribed format. [Ss. 44(6), 47(1), 50(1),(2)].

2.2 What do the directions add to the requirements of the Act for record-keeping?

i) *Content*

Although Section 44 of the Act spells out a number of details as to what is to be required in records kept by licensees, the power given in S.44(d) and S.21 is broad enough for a wide range of other records to be required, as may be outlined in the directions or these guidelines. This may be introduced into the directions or Code in the future to assist Council in the adequate monitoring and administration of the Act, but at present the directions do not add any particular detail to what must be recorded by licensees.

The records at each clinic should be kept at the discretion of each person responsible, to comply with good medical practice and other requirements of the Act, code or directions as to content.

ii) *Duration of record keeping*

The duration for which the various records are to be kept is specified in the directions as being at least 25 years.

2.3 Registers

i) *Mode of transfer of information to the register and to the Commissioner.*

The transfer of bulk **identifying information** to the register by licensees is to be electronic and once a year only, as is specified in the directions from the Commissioner, but reporting of single cases may be on the forms provided in the schedule to the directions.

The transfer of **other information** to the register is initially to be on forms issued by the Commissioner, or in printouts in the same format, but the ultimate aim is that this will be in electronic format, as may be specified in directions from the Commissioner.

Appendices 1-3 outline the flow of information to the registers, and how the information is to be kept in the registers.

ii) *Maximisation of confidentiality in transfer of identifying information about donation -*

. between licensees

Where information to be transferred between licensees includes information identifying participants, donors, or recipients and treatments undertaken, it is unadvisable for this information to be transferred in a single letter or telephone call. Those required by the directions to transfer such information should ensure that methods used maximise the confidentiality of this information, by separating identifying information from information about use and outcome.

. directly to the Register, about the use of fresh donor reproductive material or linking recipient identity with code

Identifying and non-identifying information should be transferred separately, either as the outcome is available or according to the timing given in direction 2.23. The identifying information is to be transferred in electronic format. Any correspondence including information for the registers should be addressed to the Commissioner of Health, marked 'attention Executive Officer, Reproductive Technology Council and marked 'Confidential'.

2.4 Exclusions to the requirements for a licensee to report name identifying-information to the donor register.

On compassionate grounds the directions allow for several exclusions from the requirements for licensees to register information identifying donors of gametes or embryos. These exclusions are for a transitional period, and will relate to those who began treatment prior to the Act coming into operation.

Directions from the Commissioner exclude licensees from the requirement to register donor-identifying information under the following circumstances:

a) Where prior to the Act coming into operation a woman has already achieved an ongoing pregnancy, or given birth to a child, with donor semen and has made arrangements with the Storage licensee to store semen for a repeat pregnancy by the same donor, and the Storage licensee cannot contact the donor to renew his consent, or he fails to consent under the new circumstances;

b) where, prior to proclamation of the Act, donated embryo(s) or embryo(s) derived from donated gametes have been stored for the treatment of a couple, and the donor(s) cannot be contacted by the licensee to renew consent, or the donor(s) fail(s) to consent under the new circumstances.

2.5 Why the registers are being established

The Act places on the Commissioner the responsibility to establish registers, which are to be established in the Health Department where, as the Act requires, they can be managed by public service officers specifically authorised for this purpose. The registers are being set up in the interest of those who may not act as their own advocates, such as children who may be born of the procedures, or women who may undertake the procedures in the future.

The Council recommendations to the Commissioner as to how these registers are to be managed and maintained have been made with respect for the interests of the participants in privacy, and sharing the concerns of participants and practitioners about the need for security of the information to be stored. Council has noted that any officer managing the registers is to be specifically approved by the Commissioner of Health for that purpose, and that guidelines relating to the use and management of confidential data held on these registers are based on those established by the Confidentiality of Health Information Committee (CHIC) of the Health Department of Western Australia. Name-identifying information is not to be kept on computer, but is to be held in a secure place, separate from treatment and outcome information.

A general principle guiding the use of confidential data held on these registers is that these data are not to be released to those outside the Department for research purposes. In exceptional circumstances the release of name-identifying data for such research would require the authorisation of the Commissioner, and this would only be given after the proposed study had satisfied the stringent guidelines of CHIC and on the advice of the Reproductive Technology Council, and subject to continuing monitoring procedures. The only research that the Council would recommend for approval by the Commissioner would be medical or public health research intended to provide important benefit for the health care of the community, and in line with the purpose and objects of the Act.

Any participant contacted for consent to being part of a further study may refuse to give their consent, and it should be noted that Health Department policy does not allow for the release of confidential data for social research.

However, both registers will facilitate Council in fulfilling its important functions under the Act, by providing the public, the Commissioner and the Minister, with information about the success and safety, particularly in the long-term, of the procedures undertaken. Name-identifying information is necessary to

allow certain bona-fide medical and public health research, mainly within the Health Department, which from time to time will temporarily use participant names to link information about the treatment undertaken with subsequent events, such as disease events, or allow the inclusion information from various sources, eg different hospitals. Once this linkage has been made, the name-identifying information is to be removed from the computer.

The name-identifying information on the Donor Register may also be needed to link important medical information, in relation to the donor or recipient, or to make available in the future non-identifying information to donor or child, as provided for by the Act.

Section 46 of the Act grants to the donors of any reproductive material, and to any child born as a result, rights of access to non-identifying information about each other, and the Donor Register will facilitate this process. The information sought from this register may be of medical or personal significance to the person seeking it.

It cannot be ruled out, however, that in the future another Act may grant access to identifying information stored in the Donor Register, and any person giving consent to donate or use donated human reproductive material should be aware of this possibility. No such legislation would be introduced without the opportunity to debate this controversial issue, and no stated policy proposes that access to these registers should be allowed retrospectively.

2.6 The Annual Report

The Annual Report from licensees is to include at least the information outlined in the directions (directions 2.25-2.28), with any additional information specified in the Code or directions from the Commissioner. It is likely that the first Annual Report may require more comprehensive information than subsequent Reports, as ultimately statistical information will be available through the registers.

SECTION 3: CONSENT

3.1 What does the Act say about consent for the keeping or use of gametes, eggs in the process of fertilisation of embryos?

Any licensee keeping or using gametes or embryos needs to be familiar with and comply with the requirements on consents in the Act [Ss.22 (1)(a)-(e)and 24], and the following summary does not replace a full interpretation of the Act.

. **In summary :**

- Gametes must only be used or stored with effective consent to the use or storage, and used or stored in accordance with this consent [S.22(1)(a),(b)];
- where the gametes are to be used for an IVF procedure, the consent must include consent as to what use any resultant egg in the process of fertilisation or embryo may be put [S.22(1)(c)];
- any egg in the process of fertilisation or embryo must only be stored if there is consent from each of the gamete providers and the egg or embryo stored in accordance with that consent [S.22(1)(d)];
- any egg in the process of fertilisation or embryo must only be used or received by a licensee or participant if there is effective consent from each of the persons whose gametes were used and if used in accordance with that consent [S.22(1)(e)];
- a consent to the storage of gametes must include consent for use or storage of any resultant egg in the process of fertilisation or embryo although, once an egg in the process of fertilisation or embryo results, any further consent required relates to the egg in the process of fertilisation or embryo and not the gametes [S.22(2)];
- a consent to use or storage of gametes, an egg in the process of fertilisation or embryo must be given on the understanding that this consent may impose conditions and, until any gametes, egg in the process of fertilisation or embryo are used, may be varied or withdrawn on notice [S.22(2)(3)(4)];

. **Additional matters in the Act about consent in relation to storage**

- Prior to storage of any gametes, egg in the process of fertilisation or embryo effective consent must be given as required by the Act [S.22(1)(b), 22(2),22(6), 22(8), 24].
- a consent to storage must specify the maximum period of storage established by the Code or directions, which under the Act is to be a maximum of three years for an egg in the process of fertilisation or embryo [S.22(6)(a)];
- a consent to keeping must give instructions as to what is to be done with the gametes, egg in the process of fertilisation or embryo if the person giving the consent is unable to vary or withdraw it [S.22(6)(b)];
- a consent to the storage of an egg in the process of fertilisation or embryo must state that the primary purpose of storage relates to the probable future implantation of that egg or embryo [S.24(1)]; and

every storage licence is subject to the conditions that any gametes, egg in the process of fertilisation or embryo can only be stored if acquired from another licensee or a person who can give effective consent to the storage [S.33(3)(a),(b)].

. **Additional matters in the Act about consent to use of an egg in the process of fertilisation or embryo for treatment**

A consent to the use of an egg in the process of fertilisation or embryo must specify one or more of the following purposes :

(a) use in providing treatment to the person giving consent, or that person and another person named together; or

(b) use in providing treatment to persons, other than the person giving consent, who are :-

(i) named in the consent; or

(ii) selected in accordance with circumstances specified in the consent, which may specify conditions subject to which the egg or embryo shall or shall not be so used, and are specified in the actual consent. [S.22(5)(a),(b), 26(1)(d)]

. **Additional matters in the Act about consent for donation**

Prior to donation of any gametes or embryo all relevant consents must be completed, as required by the Act to complete the transfer of rights to deal with or dispose of the gametes or any embryo [S.22,24,25,26].

As stated above, an embryo may only be donated to another couple who are either named or selected in accordance with circumstances specified on the actual consent (e.g..the consent may stipulate that the couple should be selected from among other infertile couples treated at the same clinic).

3.2 What do the directions add to the requirements in the Act about consent to keep or use gametes or embryos?

i) Additional matters in the directions in relation to consent for posthumous use.

As the directions (3.3, 8.6) specify that there is to be no posthumous use of gametes, it is not appropriate for any person to give consent at the time of storage for this purpose. They may only give consent for experimentation or disposal of their stored gametes in the event of their death.

However, there is no such restriction on consent being given for posthumous use of embryos.

ii) Consent in relation to allowing an egg in the process of fertilisation or embryo to succumb.

Although the Act allows for consent to be given to allow an embryo to succumb, Parliament, as spelled out in the preamble to the Act, intended that this legislation should respect the life created by these procedures.

The decision to allow an embryo to succumb is a significant one, but it may be needed when an embryo is not in a suitable condition for implantation, or a couple no longer require the embryo for their own treatment and do not wish to donate it to another couple. The licensee should decide how the embryo should be allowed to succumb, and what is to happen to it thereafter. The procedure should be sensitively devised and described.

iii) Limitations to the time gametes may be stored.

The Directions (3.2,6.5) specify that consent to store gametes must be renewed each five years, up to a maximum of 15 years. However, on a case by case basis, where the gametes a stored for the use of the gamete provider and not for donation, Council may extend this maximum period.

3.3 Who must give consent?

The Act itself in S.33(2)(e) clearly requires consent of the woman to any artificial fertilisation procedure carried out in her body, and Ss.22 and 26 specify circumstances where gamete providers or a couple on whose behalf an embryo was developed must give their consent. In addition the directions (3.4-3.6) specify, for particular circumstances, which others must also give consent.

3.4 What should be covered in consent given prior to an egg collection procedure?

Prior to the commencement of an egg collection **procedure** the effective consents given must include consent given by the woman and if relevant, her husband or partner, to the use of any eggs collected during the procedure, based on the following options :

(i) up to three, and in exceptional circumstances four, eggs may be transferred during a GIFT procedure;

(ii) any egg may be inseminated in vitro, with the intention that any embryo that develops is for treatment;

(iii) any egg may be donated to an(other) eligible couple in the treatment programme;

(iv) any egg may be donated to an ethically approved research programme, not involving fertilisation or development of an embryo;

(v) when the technology has developed an egg may be stored; or

(vi) an egg may be discarded.

3.5 What should be covered in consent given prior to an IVF procedure (other than GIFT)?

Prior to the commencement of an **IVF procedure (other than GIFT), the effective consents** given must include consent to dealing with any embryo that may develop, as follows :-

(i) up to three, and in exceptional circumstances four, embryos may be transferred during the IVF procedure;

(ii) any embryo not used in the treatment cycle may be stored for later treatment of the couple, up to a maximum of three years;

(iii) any embryo not used in the treatment cycle may be donated for treatment of another couple; or

(iv) any embryo not suitable for transfer or not used in the treatment cycle may be discarded, according to the guidelines.

3.6 How is effective consent to be given?

The Act states that to be effective a consent :-

(a) must be given in writing;

(b) any condition to which it is subject must be met;

(c) it must not have been withdrawn; and

(d) each participant giving consent must have been given relevant and suitable information and the opportunity to receive proper counselling, as outlined in the guidelines and approved by the Council, for specific circumstances [S.22(7),(8)].

3.7 What is the required format for effective consent to be given in?

Although the **format of consent forms** may vary between clinics, it must be evident to the Council that all requirements of the Act, Code and directions are met. A flow chart in Appendix 4 indicates the stages at which consent is required, and Appendix 5 includes draft consent forms, for guidance only.

SECTION 4: INFORMATION TRANSFER

4.1 What does the Act itself say about the giving of information?

The Act says that before a licensee gives effect to a consent, he/she must ensure that each participant has been given "such relevant and suitable information as is proper or as may be specifically required by the Code or directions". [S.22(7)]

4.2 How and when should information be given?

All required information must be given in the form of oral explanations by the relevant staff members, and supported by written material. Written material may need to be available at differing levels of understanding. Other methods of providing information, such as through videos or patient information nights, are also encouraged.

The person responsible should coordinate a system for the timely provision of all relevant written information, and this material should be provided so that it may be taken away from the clinic and discussed again later if the participants wish.

4.3 What information should given to participants prior to their effective consent?

i) Information about the effect of their consents .

The subject of the effect of consents and the right to deal with and dispose of gametes and embryos is covered in detail in the Act and any licensee should become familiar with S.25, 26 of the Act, as the following summary does not replace the full interpretation of the Act.

. In summary :-

- All rights to deal with or dispose of eggs or sperm remain with the gamete provider, unless there is consent to give these away, or they are used to produce an embryo when the rights vest jointly in the couple for whom the embryo was developed. [S.25, S.26(c)] (However a reading of S.22(3) indicates that this consent may be varied or withdrawn with some limitations);

- where gametes are given away to a licensee these may be used for purposes other than creating an embryo for research or as may be specified in conditions of the donation, and if conditions of donation are not met, the rights to unused gametes revert to the donor;

- each member of a couple on whose behalf an embryo was developed have the right to decide how it will be dealt with or disposed of;

- a couple with rights to decide over an embryo may donate it to another couple for treatment, if all relevant participants give effective consent;

- if a couple disagree over the use or continued storage of an embryo, the Commissioner of Health shall, on the application of either member of the couple, direct the continued storage of the embryo, until the issue is resolved by Court order or agreement;

- if one member of the couple dies, rights with respect of an embryo vest in the survivor;

- where the persons on whose behalf storage of any gametes or embryo was undertaken have died, or cannot be reached for instructions or required consent, the control and power of disposal vest in the Commissioner of Health, who must direct that the embryo be "made

available for the purpose of providing treatment for a specific recipient, unless a court of competent jurisdiction otherwise requires" [S.24(3)];

- where a consent required is not given, is not effective or is not complied with this may be grounds for disciplinary action against a licensee, but will not necessarily affect the rights of any person [S.22(9)].

ii) Information about the ability to place conditions on any consent or to vary or withdraw a consent is covered in the Act itself.

. **In summary :-**

- It is clear from the Act that any consent to use gametes or embryos, may be **conditional,** and RTAC guidelines require that any consent to a procedure must be able to be withdrawn at any time [S.22(5), (8)].

- The Act also covers in detail the rights of gamete providers and those for whom an egg in the process of fertilisation or embryo was developed, and specifies **a right to vary or withdraw this consent** [S.22(3)].

- There are however, **limitations** on the power to withdraw or vary any consent given, or to the use to which gametes or embryos may be put, and these are also specified [S.22(2),(4), S.26(1)(c),(e)]. This detail must be understood in the drafting of requirements in the Code or directions for the giving of consent in different circumstances, and make up an important component of counselling.

iii) Information about long term effects on participants

To be included in the information provided on the treatments undertaken, because of its particular concern to the women involved, is information about the potential for long-term ill effects of the fertility drugs they are taking. Information should be made provided to them from the most up-to -date studies available, in language that allows the significance of these studies to be understood.

iv) Information should be made available about the Public Health IVF and Donor registers kept under the Act, including the following:

- acknowledgment that identifying records and registers are kept, in particular that central registers are kept by the Commissioner of Health in the Health Department, to facilitate the monitoring and evaluation of the procedures;

- information that only medical or public health research involving linkage of IVF information with information kept in other Health Department registers, such as to carry out long term monitoring and evaluation of the safety of the procedures for participants and children born, may be carried out without further consent. Authorisation of any research by private researchers involving named information, would only be by the Commissioner on the recommendation of the Council, and this would only be given in line with the purposes and objects of the Act. Research that would involve further contact with any participant or any child born, or research to be published in any way that identifies a participant or child born, is subject to further special consent by the participant and may be refused.

- as confidentiality of information about their treatment is of great concern to participants, they should be informed of the measures being taken to ensure the confidentiality of this information during its transfer to, and keeping in, the central registers-

. Clinics should not at any time transfer to the register identifying information with treatment and outcome information;

. no identifying information is to be kept on the central computerised registers;

. the registers are to be held on locked micro-computers, and managed according to the standards established by the Health Department's Confidentiality of Health Information Committee; and

. any officers having authority to deal with the registered information must be specifically authorized by the Commissioner for this purpose, and subject to strict confidentiality provisions in the Act; and

. the extensive confidentiality provisions of the Act and directions also concern the way in which information should be kept by licensees.

Section 2.4 of these guidelines gives more background to the reasons why the registers have been established and the standards with which they will be managed.

v) Additional important information in relation to donation and the Donor Register

If relevant, there are many important issues to be covered in information made available about donation, including the following:

. Information drawing attention to the Artificial Conception Act for these situations

An understanding of the implications and effects of the Artificial Conception Act is essential, for both donors and recipients. It should be pointed out that the Artificial Conception Act refers to situations where the woman being treated is married, or in a stable de facto union, and her husband or partner gives consent to the procedure being undertaken. Otherwise the Act is silent as to the legal parentage of any child born through artificial conception. **This has particular importance in relation to consent to be given by a semen donor for cases where his semen may be used to treat a single woman, and the Directions (3.9) specify that any donor must give specific consent to such use.**

. Information drawing attention to the rights of access of any child born or biological parent to non-identifying information on the Donor Register

Attention should be drawn to the fact that registers are kept in the Health Department containing identifying and non-identifying information about donors and children born of donation. The right of access to non-identifying information on these registers is given to donors and donor children under the Human Reproductive Technology Act.

. Information drawing attention to the potential in the future for legislation to allow access to identifying information kept on the registers

Although current State and National policy on access to information do not support any retrospective access to information stored on registers, and any new legislation would be preceded by extensive public debate, at some time in the future legislation could be passed that would allow this access.

vi) Information should be given on any other relevant matters in the Act, directions or the Code that affect donation or storage.

There are a variety of limitations in the directions about which information may be relevant to a person giving consent.

Important limitations include:

limitations to the maximum numbers of offspring a donor may have through donation (5 donee families) (direction 8.1);

limitations on the import and export of donated material (directions 6.1 -6.4)

vii) If relevant, information about research or diagnostic tests on embryos that are subject of specific Council approval;

Where the consent relates to an experimental procedure or diagnostic test that has or specific Council approval, sufficient information about the procedure must be given to the participants, in a form that is understandable by them, to facilitate their informed consent.

SECTION 5: COUNSELLING

No detailed guidelines are to be provided at this stage with regard to counselling, as the Council considers it important that each counsellor and each clinic develop their own methods for incorporating the counsellor within the clinic routines, and for coordinating the transfer of information to participants. As yet there has been no experience under the Act and it is likely that practices will continue to develop with this experience. It is the intention of the Council to assist in this process and to monitor these developments. Once guidelines have been developed by Council, these will be made available to those responsible for each licensed practice.

The Council does, however, expect an approved counsellor within a licensed practice to be available, as required by the directions, for therapeutic counselling provided independently of the treatment process, and to network with other counsellors in the same area.

SECTION 6: USE AND STORAGE OF GAMETES AND EMBRYOS

6.1 Extension to the maximum period of storage of gametes.

Although the direction 6.5 specifies 15 years as a maximum period for storage of gametes, in exceptional circumstances, where these are stored for the gamete provider's own treatment or use, in response to a written application the Council may, on a case by case basis, give an extension.

6.2 Storage of embryos limited by the Act.

The Act specifies the maximum period for storage of embryos to be 3 years, and this may not be extended. For embryos already in store at the time the Act comes into force, this period may be calculated from the time the Act comes in.

SECTION 7: USE AND STORAGE OF GAMETES AND EMBRYOS

7.1 Treatment of single women by donor insemination

Neither the Act nor the directions prohibit the treatment of a single woman by artificial insemination, however, where this is to take place direction 3.9 specifies that the donor must specifically consent to this use of his semen, as until the Artificial Conception Act is amended the Act is silent on this type of situation, and there may be legal implications for the donor.

SECTION 8: PRACTICE ISSUES

. Practice issues in relation to donation

8.1 Payment of donors

The Act clearly prohibits payment for human reproductive material. This prohibition affects the provision of human reproductive material, such as semen straws, by Storage licensees to patients and the reimbursement of the donors. There is provision in the Act for a licensee to cover expenses incurred and for a donor to be reimbursed for reasonable expenses. However, whether this should occur and how much this should be is debatable, and the Council will review the current practices 12 months after proclamation of the Act.

8.2 Limits to the number of offspring a donor may have.

The statistical information that is available as to the genetic risks associated with accidental incest between donor offspring does not readily lend itself to accurate predictions of the risks that accompany increasing numbers of children born in a State the size of Western Australia. This is an area where specialist knowledge is evolving and the practitioner's judgement may be relevant to special situations, such as small ethnic groupings or small communities. Council therefore made its decision to limit the number of offspring based more on social than statistical issues, hence the inclusion of interstate offspring in the limit. Council is also to closely monitor and review the total number of children born under the current limits, that refer to families.

The judgement of the licensee is of particular importance where embryos are to be donated, as accidental incest between full siblings has far more serious genetic implications than between half siblings. As there are unlikely, however, to be large numbers of embryos for donation from a particular couple at this stage the directions are silent as to a limit and leaves the matter to the discretion of the licensee. Where this is to occur both donor and recipient couples should be strongly encouraged by the licensee to undergo counselling about the special implications of embryo donation.

8.3 Known donors

The use of known donors is not ruled out by the directions. However, the directions do specify that the licensee or exempt practitioner may not carry out the treatment unless any donor and the recipient and their spouse or partner must all have had at least one session of counselling with an approved counsellor. Also the directions specify what must be covered in the information that the licensees are to provide to those undergoing the procedure.

Although in these cases the directions also do not rule out the use of fresh donated material, the use of frozen and quarantined material is encouraged, and there is to be 6-month cooling off period following the initial undertaking to donated under these circumstances, and in these cases additional information must be provided to the recipients about the fallibility of HIV testing under the circumstances.

The time of initial agreement, from which the six-month cooling off period may be calculated, is taken to be the time consent is given to the procedure, following the required counselling, and should be recorded.

The sperm banks will be responsible for reporting information as to outcome back to the registers, where the reproductive material used in the procedure was supplied by them.

. Other practice issues

8.4 Repeated ovarian stimulation

As it is difficult to predict the survival rates for thawing embryos and because of the apparent improved success rate of IVF and GIFT procedures when more than one egg or embryo is transferred, it may be in the best interests of the couple being treated to allow for the possibility of carrying out a repeat egg collection cycle in spite of the fact that one or two embryos are still in storage. The regulation placed on repeated stimulation cycles is to minimise that build-up of large numbers of frozen embryos that may never be used for treatment

8.5 Posthumous use of stored reproductive material.

Direction 8.6 very clearly specifies that there is to be no known posthumous use of gametes. One implication of this is that when a person gives consent at the time of storage of their gametes they may not as an option for after their death specify that their gametes may be used for treatment of another. They may only choose that their gametes be used for experimentation or discarded.

However, nothing in the Act or the directions rules out a couple giving consent for posthumous donation of an embryo for treatment of another couple.

SECTION 9: RESEARCH AND DIAGNOSTIC TESTING

NOTE: Directions 9.1-9.3 relate generally to all routine clinical and laboratory procedures, all research and all diagnostic testing, including embryo research or testing. However additional criteria, relating to documentation of the therapeutic nature of this research or test and its non-detrimental effects, must also be met for approval of embryo research or tests, as directed by directions 9.4-9.5.

9.1 Guidelines as to TIMING of approvals to be sought

(i) At the time of licensing

General approval of all routine clinical and laboratory procedures or specific approval for innovative clinical or laboratory procedures, research or embryo diagnostic procedures may be given at the time of licensing.

Routine procedures in place at the time of licensing may be given the general approval of Council if they comply with Council standards in the guidelines for general approval. At the time of application for a licence a fully documented manual, containing details of all clinical and laboratory procedures used in the clinic, must be made available to the Council, and all or part of this may be sent by Council to RTAC for review. **General approval given at this time may include approval for routine quality assurance procedures and routine audit of procedures.** Guidelines given below indicate in general the standards to be met for a procedure to be eligible for general approval.

At this time application should be made for the **specific approval** of any clinical or laboratory procedure that according to the guidelines set out below would be considered innovative. It should be noted that for **all specifically approved procedures** there must be adequate written information available for participants giving consent to these procedures. The initial process of application for specific approval of research or embryo diagnostic procedures will also be made at this stage.

All applications for specific approval at the time of licensing should be made on a **special application form**, available from the Executive Officer and shown here in **Appendices 6, 7 and 8.**

ii) Later approvals sought by licensees

General approval for variation to procedures that are considered by licensees using the guidelines set out below to be eligible for general approval , or **specific approval** of procedures that are innovative, research or embryo diagnostic procedures may be sought at any time.

However, a new procedure that appears to the person responsible to fit the criteria for **general approval** may be introduced into practice if it is fully documented in the procedure manual and this is available, on request, to the Council for its formal approval. If a licensee is in any doubt as to whether a proposed change would fit the criteria they should request advice from the Council.

As indicated in the directions, Council may or may not agree with the judgement of the licensee that the new procedure is routine, may or may not grant its general approval when the manual is reviewed and may or may not require the new procedure to be withdrawn.

At any time also application may be made for **specific approval** for any new research, new diagnostic procedures involving embryos, or for subsequent changes to the clinical or laboratory procedures that are considered innovative, and these applications must be made in the relevant format, as shown here in Appendices 6, 7 and 8 and as available from the Executive Officer.

9.2 Guidelines for licensees to STANDARDS for GENERAL or SPECIFIC approval

The guidelines below are to assist licensees in deciding whether to assume general approval or to seek specific approval for procedures or changes to the approved routine protocol.

i) Standards for general approval

General approval may be assumed likely where documentation can 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 NH MRC Statement on Human Experimentation and Supplementary Notes;
- has not been rejected by the relevant IEC;
- is used in other reputable, nationally or internationally recognised clinics (details given);
- is reported in international peer - reviewed literature, indicating safe and successful outcome, based on good research (references to be supplied);
- 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; and
- if relating to any embryo, is intended to be therapeutic for the embryo and is unlikely to be detrimental to its well-being.

ii) Standards for specific approval

Specific approval *must* be sought for any research or any diagnostic procedure involving an embryo, or any clinical or laboratory procedure which -

- has not been adequately reported in the literature; or
- is not widely used in other reputable, nationally or internationally recognised clinics; or
- is a totally novel project, not yet reported, but with relevant ethical approval; or
- it is not yet evident it will be successful in the local clinic (no prior training or experience).

Where the application for approval relates to a specific approval, application must be made in the format outlined in the Appendix, details must be given of any application for approval by the relevant IEC and the outcome of that application, and there must be an undertaking not to proceed with the proposed change without notification of Council approval.

9.3 Additional guidelines for licensees to research on embryos

(i) All those using embryos must be fully aware of the relevant prohibitions and offences in section 7 of the Act.

(ii) there is no 'window' for non-therapeutic research prior to syngamy;

As the directions prohibit the development of any egg in the process of fertilisation or embryo other than with the intention of its probable future implantation, this means that there is no window of opportunity for

non-therapeutic research, even in the early stages of fertilisation prior to syngamy [S.17(b)]. This is in contrast to the situation under the Victorian Act.

(iii) any embryo created is to be for implantation;

The directions must (as directed by the Act) prohibit the development of any embryo solely for research or diagnostic testing. The intention to implant any resultant embryo is to be indicated through the consent given by the participants, indicating this as their understanding.

(iv) the research must be intended to be therapeutic, and not likely to be detrimental to any embryo;

The Act prohibits research on an embryo that has not had Council approval. Furthermore, Council may not grant this approval unless the research is 'intended to be therapeutic' and existing scientific and medical knowledge indicates there is not likely to be any detrimental effect on any embryo [S.7(1) read with S.14(2) and [S.20(2), (3)].

Therapeutic research refers to research likely to benefit the embryo. This must relate to the individual embryo and is of course tied in with the corollary that any experiment will also not be detrimental to the embryo.

If scientific documentation provided with the application for approval indicates that the research procedure will result in, or can reasonably be expected to result in, embryos that are competent for implantation and unlikely to be damaged by that research procedure, the procedure may be considered for approval.

Non-therapeutic research on embryos is that which is:

. destructive - where outcome is that the embryo is killed or completely unsuitable for implantation by the criteria generally accepted in the field;

or

. where the likelihood of successful implantation is significantly reduced.

(v) general approval to routine procedures involving embryos may be given;

The offence in S.7(1) of the Act refers to 'relevant' and 'specific' approval for embryo research. However general approval may be given to quality control procedures or audit procedures involving embryos where these are not experimental.

At the time of initial approval of the licence, general approval may be given by Council to these routine procedures as documented in the protocol manual submitted. And subsequently, on fully documented application in the required format as outlined below, variations to the routine protocol, including procedures involving embryos, may be eligible for further general approval by Council.

To be eligible for general approval any routine variations to laboratory or clinical practices, quality control procedures etc. must be fully documented, including evidence that the variations fulfil all the above criteria relating to the non- experimental, therapeutic and non-detrimental nature of the proposed procedure, and that they meet the standards for general approval.

(vi) specific approval must be sought for any proposed embryo research not eligible for general approval.

The guidelines for application for specific approval of proposed embryo research are similar to those detailed below for all research, although additional criteria relating to the therapeutic and non-detrimental nature of the research also apply.

(vii) counselling and consent are required;

The Act requires the provision of counselling and the giving of effective consent for any research involving embryos [S.22].

The consent signed by the participants for any embryo research should indicate their understanding of the likely outcome of the procedure and their intention that the embryo would subsequently be implanted.

The directions and explanation on counselling and consent are covered in Sections 3, and 5 of the directions and these guidelines.

(viii) the standards for approval of embryo research must be met and the required process of application followed;

The details to be required in the protocol manual submitted at the time of initial licensing, as well as guidelines for application for approval of variations to this, are outlined in the section on general research. The guidelines for application for specific approval of proposed embryo research are similar to those detailed below for all research, although additional criteria relating to the therapeutic and non-detrimental nature of the research also apply.

Application forms for approval are shown in Appendices 10-12.

9.4 Guidelines for licensees on diagnostic testing of embryos

(i) The test is not to be detrimental to any embryo

It is to be an offence for a licensee to carry out a diagnostic test involving an embryo without Council authorisation or specific approval. According to S.14 of the Act, this may not be given unless the procedure is intended to be therapeutic for the embryo concerned and, based on existing knowledge, 'no detrimental effect on the well - being of any egg in the process of fertilisation or embryo is likely thereby to occur'.

The interpretation of whether the procedure is likely to fulfil these criteria is to be based on the scientific documentation given with the request for approval, with a similar interpretation of 'therapeutic' and 'detrimental' to that outlined in the above guidelines for embryo research.

(ii) certain diagnostic procedures involving embryos may be authorised

The Code may include provisions, in general, as to which diagnostic procedures should, or may, be undertaken prior to the commencement of an artificial fertilisation procedure [S.21(b)]. It also may specify what diagnostic procedures involving embryos may be authorised, that is do not require specific approval [21(k)]. In order to be so authorised, however, any procedure would have to fill all required criteria.

For applications for authorisation or specific approval of diagnostic tests involving embryos, the process of application and standards that apply are as for the general or specific approval of all experimentation, but with additional criteria to be met, as for embryo research.

(iii) counselling and consent are required for testing of embryos

The Act requires there to be counselling and consent under all circumstances where there is to be any use of an embryo, and this would include diagnostic testing [S.22(e)].

Counselling and consent are covered in Parts 3 and 5 of the directions and these guidelines.

(iv) the standards for approval must be met and the required process of application followed

At the time of initial approval of licence, general authorisation may be given by Council to routine embryo diagnostic procedures documented in the protocol manual submitted. Subsequently, on fully documented application in the required format as outlined below, variations to the routine protocol, including new diagnostic procedures involving embryos, may be eligible for further general authorisation by Council.

To be eligible for general authorisation, any routine diagnostic procedure involving embryos, such as routine observations, must be fully documented, including evidence that the tests fulfil all the criteria relating to the therapeutic and non-detrimental nature of the proposed test as for embryo research.

The details to be required in the protocol manual submitted at the time of initial licensing, as well as guidelines for application for approval of variations to this, are outlined below in the section on general research.

Application forms for approval are shown in Appendices 10-12.

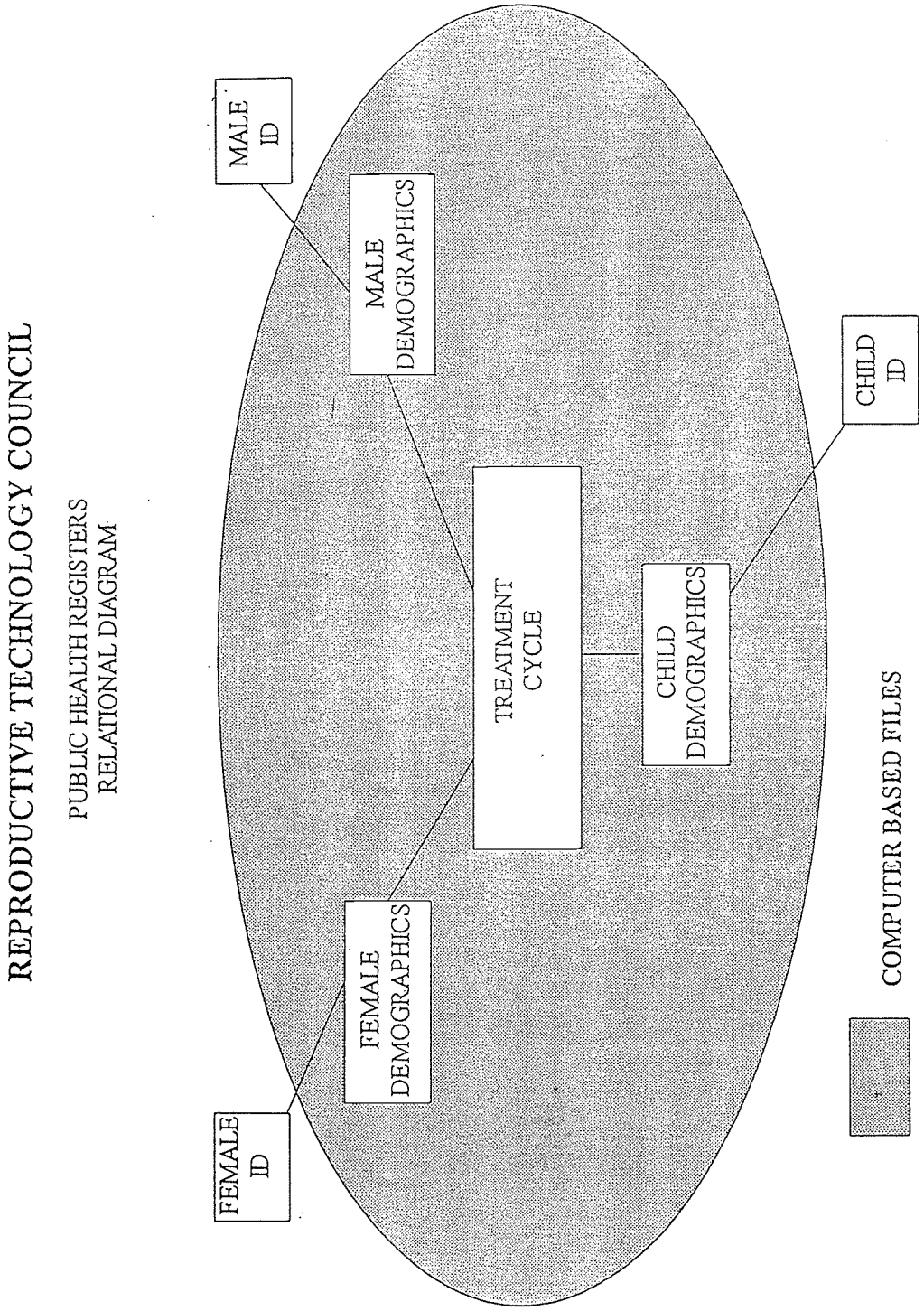
The requirements for counselling and consent in these circumstances are covered in Sections 3, and 5 of the directions and these guidelines.

(v) Certain procedures are not considered to be diagnostic procedures.

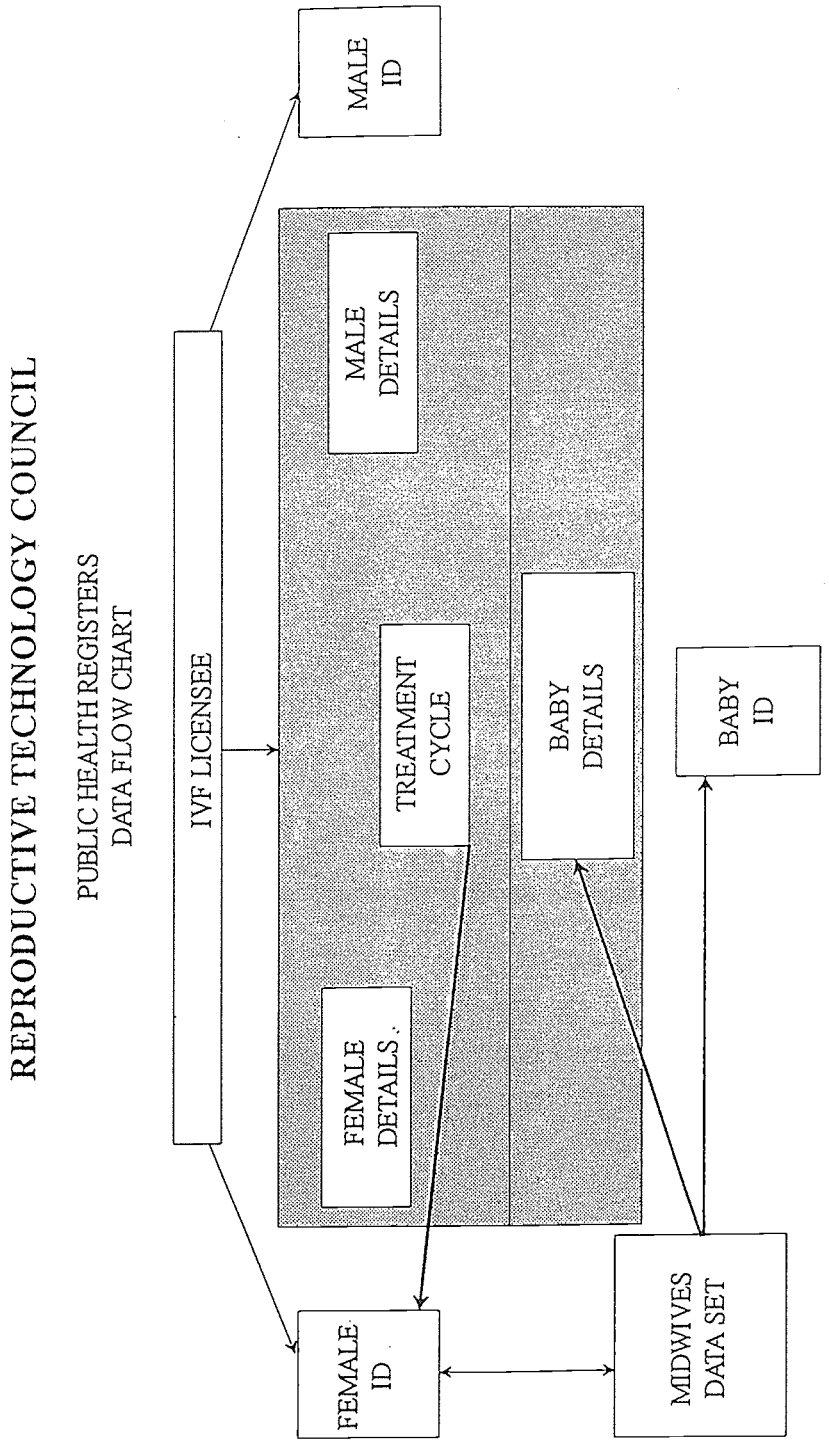
Two standard procedures are not considered to be diagnostic procedures, these are:

- observation of oocytes for evidence of fertilisation; and
- observations made to determine whether an embryo is still developing or still alive.

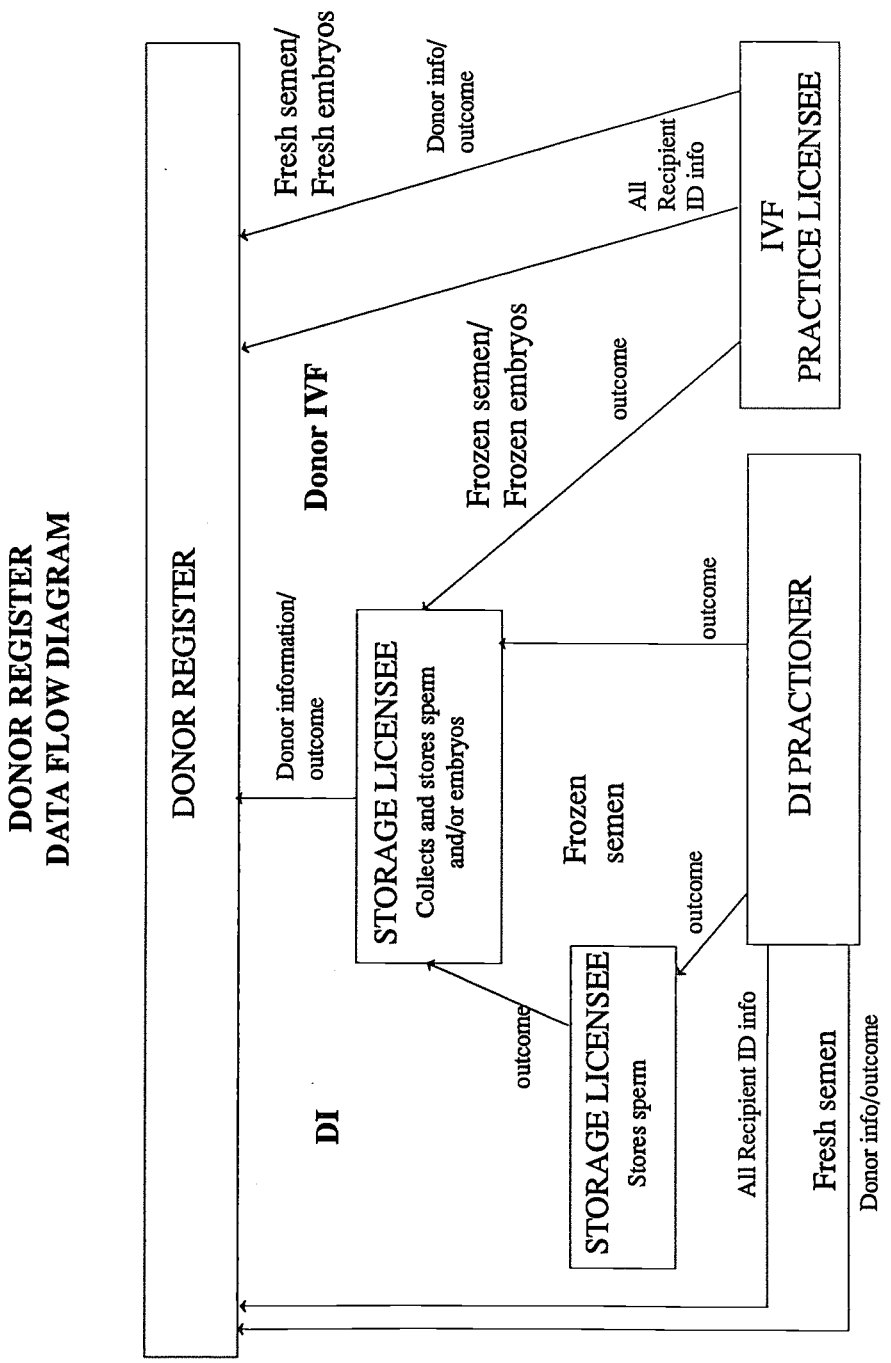
APPENDIX 1 PUBLIC HEALTH REGISTERS RELATIONAL DIAGRAM



APPENDIX 2 PUBLIC HEALTH REGISTERS DATA FLOW CHART



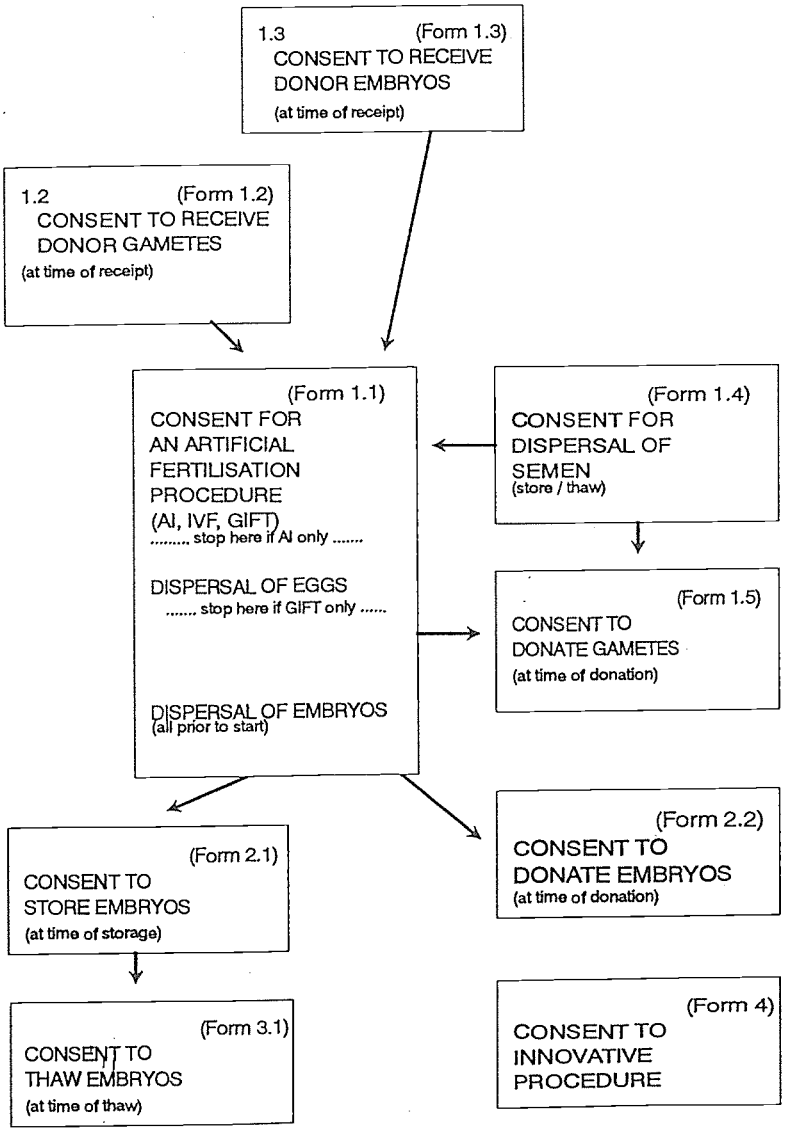
APPENDIX 3 DONOR REGISTERS DATA FLOW CHART



APPENDIX 4

FLOW CHART OF CONSENT REQUIRED

FLOW CHART FOR CONSENT REQUIRED UNDER THE HUMAN REPRODUCTIVE TECHNOLOGY ACT



APPENDIX 5
DRAFT CONSENT FORMS

Form 1.1

PATIENT CONSENT FOR AN ARTIFICIAL FERTILISATION PROCEDURE[1]

PART A:
TO BE FILLED IN BY ALL THOSE UNDERTAKING AN ARTIFICIAL FERTILISATION PROCEDURE, WHETHER ARTIFICIAL INSEMINATION, IVF, GIFT OR A RELATED PROCEDURE.

I/We:.....
.....and
.....
.....

consent the procedure known as:

and understand that the protocol for this procedure is considered to be suitable medical practice, and that any steps that are experimental or innovative require specific consent on a separate form.

I/We agree that:

1. I/We have read information about this procedure provided by the Centre, which describes the procedure with its possible risks, complications, unwanted effects and likelihood of success;

2. I/We have discussed the procedure with staff of the Centre; and

3. if I/we intend to use donor gametes, or any donor embryo[2], or to donate them, we have filled in the appropriate consent form [1.2 or 1.3 to receive donated gametes or embryos, or 1.5 or 2.2 to donate gametes or embryos].

IF UNDERTAKING ARTIFICIAL INSEMINATION ONLY, DO NOT FILL IN PART B OR PART C OF THIS FORM, BUT PROCEED NOW TO PART D.

[1] An "artificial fertilisation procedure" under the Human Reproductive Technology Act (1991) includes artificial insemination, as well as IVF and all related procedures, such as GIFT.

[2] Any reference to an embryo includes a reference to an egg in the process of fertilisation.

PART B:

IF UNDERTAKING IVF, GIFT OR A RELATED PROCEDURE THIS PART MUST BE FILLED IN.

In undertaking this IVF, GIFT or related procedure,

We-

(a) agree that there is to be a maximum of three (or in exceptional circumstances four) embryos or eggs that we may have transferred; and

(b) declare that we are married, or have been living together in a defacto relationship for 5 of the last 6 years.

We understand that if there is any egg recovered during the IVF or GIFT attempt, the options available regarding that egg are as follows:

1. Up to three (and in exceptional circumstances four) eggs may be transferred in a GIFT procedure;
2. it may be inseminated in vitro, with the intention that any embryo developed is for our treatment;
3. it may be donated to an eligible couple in a treatment program;
4. it may be donated to an ethically approved research program, not involving fertilisation or development of an embryo;
5. when the technology has been developed it may be stored; or
6. it may be discarded.

At present we choose to have any eggs collected in this procedure used in the following way:.....

.....

.....

.....**but we understand we have the right to vary or withdraw this consent, [in writing] prior to the use or discarding of any egg.**

If we are undertaking a procedure using donor egg embryos or donor embryos we have filled the consent forms 1.2 or 1.3.

WE WISH TO PLACE THE FOLLOWING CONDITIONS ON OUR CONSENT:

.....

.....-

IF YOU ARE UNDERTAKING NOT TO HAVE ANY EGG INSEMINATED, THAT IS IF YOU ARE UNDERTAKING GIFT ONLY, THERE IS NO NEED TO FILL IN PART C OF THIS FORM, BUT PROCEED NOW TO PART D.

PART C:
TO BE FILLED IN ONLY BY THOSE UNDERTAKING TO HAVE ANY EGG FERTILISED, AS PART OF IVF OR A RELATED PROCEDURE.

We request the Centre and its staff to inseminate one or more of the eggs that may be collected during the IVF procedure and not otherwise used or discarded at our request, and we understand that, under the Human Reproductive Technology Act 1991, the development of any embryo must be with a view to its future implantation.

We request that (a) donor sperm, or (b) sperm of the husband named above

(delete as appropriate)

are to be used for the insemination, and understand that the gametes must not be mixed in such a way as to allow confusion as to the biological parentage of any child that may be born as a result.

If we elect to use donor sperm we have completed consent form 1.2.

If any embryo develops, we understand our options are that:

1. Up to 3 (and in exceptional circumstances 4) embryos may be transferred fresh during an IVF procedure;
2. any embryo not used in this treatment cycle may be stored for our later treatment, up to a maximum of three years;
3. any embryo not used in this treatment cycle may be donated for treatment of another couple; or
4. any embryo that is not suitable for transfer, or not used in this treatment cycle, may be allowed to succumb, according to Guidelines of the Code of Practice under the Human Reproductive Technology Act 1991.

At present, our request for the distribution of any embryos that develop, is as follows:

.....

.....

.....

.....,

but we understand we can withdraw or vary this request (in writing) at any time, prior to the use or succumbing of any gametes or embryo.

If we have chosen to have any suitable embryos stored, we have filled in consent form 2.1, and if we are electing to donate any available embryos, we have filled in consent form 2.2.

PART D:
TO BE FILLED IN BY ALL WHO ARE TO UNDERGO AN ARTIFICIAL FERTILISATION PROCEDURE.

We understand that:

1. The procedure may not achieve its desired aim;
2. cancellation or abandonment of the procedure or transfer to another procedure may be necessary;
3. we are free to vary or withdraw our consent at any time [in writing] prior to the disposal or use of gametes or embryo that are the subject of our consent.

Each of the above points has been explained to us by:

.....[please print name]

.....[signed]

Woman.....[signed]

Witness.....[signed]

Husband (Partner).....[signed]

Witness.....[signed]

Dated:.....

Form 1.2

CONSENT TO RECEIVE DONATED GAMETES (SPERM OR EGGS) FOR TREATMENT

NAME OF WOMAN: .....

NAME OF HUSBAND (PARTNER): .....

ADDRESS: .....

.....

In consideration of the Centre allowing to participate in its donor gamete program, we have read information concerning this program and have had opportunity to discuss issues related to the use of donor gametes with staff of the Centre, and we understand that:-

1. Despite the exercise of all reasonable care and professional skill, there are risks associated with the treatment. If pregnancy should result, there is a possibility of complications of childbirth or delivery of a physically, mentally or psychologically abnormal child or a child with unsuspected hereditary illness or characteristics;

2. if the donation is anonymous the identity of any donor shall not be disclosed to us, nor shall the clinic staff reveal the identity of me/us or any child to the donor;

3. records are kept by the Centre and in a central register in the Health Department of WA, whilst subject to the usual confidentiality of medical records and requirements of the Human Reproductive Technology Act 1991, may be subpoenaed by a court of law;

4. under the Human Reproductive Technology Act 1991 any child born as a result of this treatment may have access to non-identifying information relating to the donor, and that another written law in the future may grant access of the child to identifying information;

5. under the Artificial Conception Act (1985) any child born to a married or defacto couple following a procedure involving donated human reproductive material which has the husband's consent shall be treated in all respects including descent of property, duties of support and maintenance as if the child were a natural child of that couple; and

6. the donor may withdraw or vary consent, prior to use of the gametes.

Each of the above points has been explained to us by: .....[please

print name].....[signed]

Woman:.....Witness:.....

Husband (partner):.....Witness:.....

Dated:.....

Form 1.3

CONSENT TO RECEIVE DONOR EMBRYO(S)[2] FOR TREATMENT

NAME OF WOMAN: .....

NAME OF HUSBAND (PARTNER): .....

ADDRESS: .....

.....

.....

We have read the information provided by the Centre and have had the opportunity to discuss these issues with the staff.

We understand that another couple has donated to us ..... (number) embryo(s) for our treatment and in requesting the receipt of them we understand that:

1. Despite the exercise of all reasonable care and professional skill, there are risks associated with the treatment. If pregnancy should result, there is a possibility of complications of childbirth or delivery of a physically, mentally or psychologically abnormal child or a child with unsuspected hereditary illness or characteristics;

2. if the donation is anonymous the identity of the donor shall not be disclosed to us, nor shall the clinic staff reveal the identity of us or any child born to the donors;

3. the donors may vary their consent (in writing) at any time prior to the use of the egg(s) in the process of fertilisation or embryo(s) or expiry of storage limit under the Human Reproductive Technology Act 1991;

4. records of the donation are to be kept at the Centre and in a register in the Health Department of WA and, although subject to the usual confidentiality of medical records and the requirements of the Human Reproductive Technology Act 1991, could be subpoenaed by a court of law;

5. under the Human Reproductive Technology Act 1991 any child born as a result of the donation may have access to non identifying information about the donors and a
subsequent written law may provide any such child access to identifying information about the donors; and

6. under the Artificial Conception Act (1985) the child is legally our child.

Each of the above points has been explained to us by: .....

[please print name].....[signed]

Woman: ..... Witness:.....

Husband (partner): ..... Witness:.....

Dated: .....

[2] Any reference to an embryo includes a reference to an egg in the process of fertilisation.

Form 1.4

CONSENT TO USE SEMEN

NAME OF MAN .....
.....

ADDRESS .....
.....

I have read the information provided in relation to the use of my semen, and have had the opportunity to discuss issues raised with staff of the Centre.

This request relates to dispersal of my (a) fresh (b) frozen semen (delete as applicable).

I understand that my semen may be used in the following ways:

1. Fresh or thawed semen may be used in my own treatment (AIH - artificial insemination of my partner);

2. it may be stored for my own treatment, but only according to any time limits to the storage of semen in this State set under the Code of Practice of the Human Reproductive Technology Act 1991 and otherwise according to the commercial arrangement between me and the Centre;

3. I may donate it, as approved under the Human Reproductive Technology Act 1991, for the treatment of infertility or genetic abnormality in others, and if I choose this option, whereby a child may be born, my wife or partner (if any) and I must fill in consent form 1.5;

4. it may be used for research, not involving the development of an egg in the process of fertilisation or embryo; or

5. it may be discarded.

At present I choose option/s ..... but understand I may place conditions on my consent and may vary or withdraw this consent [in writing] at any time up to disposal or use of the semen.

CONDITIONS ON OPTION/S SELECTED.....

.....

If at some time in the future I am unable, by reason of incapacity or otherwise, to vary the terms of this consent or withdraw it I would like any semen stored on my behalf to be used for

approved research/discarded/

(delete if not applicable).

Each of the above points has been explained to me by:.....

.....[please print name]

Man:..... Witness:.....[signed]

Dated:.....

Sample nos. of any semen samples

stored: _____

_____

_____

or

thawed: _____

_____

_____

Form 1.5

CONSENT TO DONATE GAMETES (EGGS OR SEMEN) FOR TREATMENT

Name of gamete donor: .....

Name of Spouse (partner) if any: .....

Address: .....

.....

In offering my services as a gamete donor, (that is a donor of semen containing sperm cells or any egg) for the treatment of infertility or a genetic disorder as approved under the Human Reproductive Technology Act 1991, I understand that a child may thereby be born.

I agree that I have read the information provided by the Centre covering issues raised by gamete donation and have had the opportunity to discuss these issues with staff of the Centre.
I understand that:

(1) Each donation of semen or any egg will require a statutory health/lifestyle declaration;

(2) for the purposes of determining whether I am acceptable, I may have to undergo a physical examination including the taking of blood and other body fluids and an enquiry into my family history for the purpose of obtaining non-identifying information;

(3) if the donation is to be anonymous the identity of any recipient shall not be disclosed to me, nor shall the staff of the Centre voluntarily reveal my identity to any recipient or their partner and I will not seek the identity of any child born as a result of my donation;

(4) under the Artificial Conception Act (1985) when the husband consents to the donation any child born as a result of donation of human reproductive material will be the legal child of any married or defacto couple of which the treated woman is part, and the donor has no legal status of paternity or maternity.

(5) that records are kept by the Centre and in registers in the Health Department of WA, and whilst subject to the usual confidentiality of medical records and the requirements of the Human Reproductive Technology Act 1991, may be subpoenaed by a court of law; and

(6) under the Human Reproductive Technology Act 1991 any child born as a result of my donation may have access to non-identifying information about me.

To the best of my knowledge, information and belief:

(a) None of my immediate family is known by me to have suffered from any physical or mental hereditable disorders;

(b) I am in good health, have no communicable disease and I do not suffer from any major physical, mental or psychological disorder;

and I have completed the form for confidential screening of donors.

I agree that, unless I specify otherwise in writing, there are no conditions on my donation concerning the use of the gametes and that my gametes may be stored and/or used in an IVF procedure, and I understand at any time up until the gametes have been used I may vary or withdraw my consent.

Conditions of donation.....

.....

.....

.....

.....

(For a male donor only)

I do/do not consent to the use of my semen in any artificial fertilisation procedure to which section 6 of the Artificial Conception Act does not apply.

Each of the above points has been explained to me by: .....[please print name].....[signed]

Donor:.....Witness:.....

Spouse (Partner)(if any):.....Witness:.....

Dated: .....

Form 2.1

CONSENT FOR STORAGE OF EMBRYOS[2]

NAME OF WOMAN: .....

NAME OF HUSBAND (PARTNER): .....

ADDRESS: .....

.....

.....

We have read the relevant information provided by the Centre and have had the opportunity to discuss the issues raised with the staff. We request the Centre and its staff to store by freezing (cryopreservation) any suitable embryo not otherwise used in this treatment cycle, according to our request. We confirm that we understand and consent as follows:

1. Under WA's Human Reproductive Technology Act 1991 the principal aim of storage of any embryo must be to allow further attempts at pregnancy at a later date;

2. storage is to continue for a maximum period of three (3) years and at this stage we opt to store for a maximum of ..... years; and

3. under the Human Reproductive Technology Act 1991 -

   in the event that one partner dies, the remaining partner has the right to decide over disposal of the embryo(s);

   in the event we both die without leaving any other instructions, the Commissioner of Health has the power to make our frozen embryo(s) available for treatment of a specific recipient unless a court orders otherwise; and

   if we disagree about the use of the embryo(s) the matter may be resolved by a Court, but prior to this resolution the Commissioner of Health can direct continued storage of the embryo(s) up to the limit of 3 years, upon payment of proper charges to the licensee for this.

If we both should die our wishes at this stage are that any embryo stored in our names is:

(a) made available by the Commissioner for providing treatment to another couple eligible under the Human Reproductive Technology Act 1991;

(b) donated to specific couple for treatment; or

(c) allowed to succumb.

At present we elect to use option a/b/c (delete if not applicable), although we reserve the right to vary or withdraw this option [in writing] at any time, prior to the use or succumbing of any embryo.

CONDITIONS OF DONATION (optional) e.g. criteria for selection of recipient couple.

.....

We hereby consent to have our embryo(s) stored, in the light of the above guidelines, although we understand that we may vary or withdraw this consent (in writing) at any time.

Each of the above points has been explained to us by:.....

.....[please print name].....[signed]

Woman: ..... Witness:.....

Husband (partner):..... Witness:.....

Dated: .....

[2] Any reference to an embryo includes a reference to an egg in the process of fertilisation.

Technology Act.

Embryo ID	Date of storage	Expiry date for storage	Date of removal from storage/transfer *

* See consent form 3.1 for further details.

Form 2.2

CONSENT TO DONATE EMBRYO(S)[2] FOR TREATMENT

NAME OF WOMAN: .....

NAME OF HUSBAND (PARTNER): .....

ADDRESS: .....

.....

We request to donate ..... (number) embryo(s), no longer needed for our own treatment, for the treatment of another couple that is either named below, or selected in accordance with circumstances specified in this consent.

We have read the information provided by the Centre and we have had the opportunity to discuss issues related to this donation with staff at the clinic.

We understand that:

1. Records relating to this donation are to be kept by the Centre and in a register in the Health Department of WA, and although subject to the usual confidentiality of medical records and the requirements of the Human Reproductive Technology Act 1991, may be subpoenaed by a Court of Law;

2. under the Artificial Conception Act (1985) any child born as a result of this donation will be the legal child of a couple to which it is born when the husband consents to the procedure;

3. under the Human Reproductive Technology Act 1991 any such child would have access to non identifying information about us kept in the register and a later written Act may give that child access to identifying information about us; and

4. we may withdraw or vary our consent at any time prior to the use of any embryo(s).

CONDITIONS.....

SPECIFIED CIRCUMSTANCES FOR SELECTING THE RECIPIENT COUPLE:

.....

.....

Each of the above points has been explained to us by: .....[please print name]

.....[signed]

Woman: ..... Witness: .....

Husband (partner): ..... Witness: .....

Dated: .....

[2] Any reference to an embryo includes a reference to an egg in the process of fertilisation.

Form 3.1

CONSENT FOR USE OF STORED EMBRYOS[2]

NAME OF WOMEN: .....

NAME OF HUSBAND(PARTNER): .....

ADDRESS .....

We request the Centre and its staff to deal with .....(number) of embryos held in storage at the Centre.

(ID's of those to be dealt with .....)

We understand our options are:

1. to have them thawed and implanted in an IVF procedure for our treatment, using a maximum of 3 (and under exceptional circumstances 4) in this procedure.

2. to donate them to another couple for their treatment;

3. To direct the clinic to allow the embryo(s) to succumb;

We choose option ..... and have had the opportunity to discuss its ramifications with a counsellor approved by the Reproductive Technology Council, and understand we may vary our consent (in writing) until any embryo has been used or allowed to succumb.

CONDITIONS .....

Each of the above points has been explained to us by: .....

[please print name].....[signed]

Woman: ..... Witness:.....

Husband (partner): ..... Witness:.....

Dated: .....

[2] Any reference to an embryo includes a reference to an egg in the process of fertilisation.

Form 4

CONSENT TO AN EXPERIMENTAL OR INNOVATIVE PROCEDURE

.... Project Title and brief description
....
.....
.....
....

I/we have read the information provided to us by the Centre about this experimental or innovative procedure. I/we have had the opportunity to discuss this project with staff of the Centre. I/we herewith give consent for:

use of my egg(s); or
my sperm; or
any of our egg(s) in the process of fertilisation or embryo(s)[1]; or
my personal involvement
(delete as appropriate)

in this project.

I understand I may withdraw this consent at any time [in writing] prior to use of any gametes, egg(s) in the process of fertilisation or embryo(s).

CONDITIONS OF CONSENT .....
.....
.....
....

Each of the above points has been explained to us by: .....[please print name]..... .[signed]
Woman:..... Witness:..... .....
Husband (partner): ..... Witness:.....
Dated: .....

APPENDIX 6

APPLICATION FORM FOR APPROVAL FOR RESEARCH TO BE CARRIED OUT UNDER A PRACTICE/STORAGE LICENCE ISSUED UNDER WA'S HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

Note: Prior to implementation of Act this research may be current, otherwise must have approval prior to being done.

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

Name of Licensee: _____

_____

Person responsible: (Full name) _____

Address: _____

_____

_____

Tel: _____

Fax: _____

Institutional 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)

issued: _____ (Date)

Signed: _____ (Chairman, Reproductive Technology Council

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

Before completing please read the relevant sections of the Code of Practice relating to Research and diagnostic testing under WA's Human Reproductive Technology Act 1991.

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:

(1) participant(s);

(2) sperm or eggs intended for use in an artificial fertilisation procedure;

(3) eggs in the process of fertilisation or embryos.

(3) Whether IEC approval has been sought and if so, provide comments made on the proposal by the relevant IEC.

(4) With evidence that the procedure to be adopted complies with the standards set out in the NH MRC statement on Human Experimentation and supplementary notes.

(5) If the research is involving an egg in the process of fertilisation or embryo give evidence supporting the fact that

(a) the proposed research is intended to be therapeutic for the egg or embryo concerned; and

(b) that existing scientific and medical knowledge indicates that no detrimental effect on the wellbeing of any egg in the process of fertilisation or embryo is likely thereby to occur.

(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 (09) 222 4260
Fax (09) 222 4236

APPENDIX 7

APPLICATION FORM FOR SPECIFIC APPROVAL FOR A DIAGNOSTIC PROCEDURE TO BE CARRIED OUT UPON OR WITH AN EGG IN THE PROCESS OF FERTILISATION OR EMBRYO

APPLICATION FORM FOR SPECIFIC APPROVAL FOR A DIAGNOSTIC PROCEDURE TO BE CARRIED OUT UPON OR WITH AN EGG IN THE PROCESS OF FERTILISATION OR EMBRYO

Name of Licensee: _____

Person responsible: (Full name) _____

Address: _____

_____

_____

Tel: _____

Fax: _____

Institutional Ethics Committee: _____ \ _____
Chairman (Name)

Type of diagnostic procedure for which specific approval is sought:

_____

_____

Reference No: _____ (for office use only)

issued: _____ (Date) _____

Signed: _____ (Chairman, Reproductive Technology Council)

DETAILS OF PROPOSAL TO CARRY OUT AN EMBRYO DIAGNOSTIC PROCEDURE

Before completing please read the relevant sections of the Code of practice relating to diagnostic testing under WA's Human Reproductive Technology Act 1991.

SUMMARY (NOT MORE THAN 1,000 WORDS).

Please specify:

(1) Whether diagnostic procedure is to be carried out by the licensee or facilitated by them, and if so who will carry it out.

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

(3) With evidence, that the procedure to be adopted complies with the standards set out in the NH MRC statement on Human Experimentation and supplementary notes

(4) With evidence, that

(a) the proposed diagnostic procedure is intended to be therapeutic for the egg or embryo concerned; and

(b) that existing scientific and medical knowledge indicates that no detrimental effect on the wellbeing of any egg in the process of fertilisation or embryo is likely thereby to occur.

(5) Full details of the proposal.

(6) 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 (09) 222 4260
Fax (09) 222 4236

APPENDIX 8

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

Name of Licensee: _____

_____

Person responsible: _____
(Full Name)

Address: _____

_____

_____

Tel: _____

Fax: _____

Institutional Ethics Committee: _____
Chairman (Name)

New/ modified procedure for which SPECIFIC approval is sought:

_____

_____

Reference No: _____(foroffice use only)

_____(Signed, Chairman Reproductive Technology Council)

Issued, Date: _____

DETAILS OF PROPOSAL FOR SPECIFIC APPROVAL OF AN INNOVATIVE PROCEDURE

Before completing please read the relevant sections of the Code of practice relative to research and diagnostic testing under WA's Human Reproductive Technology Act 1991.

SUMMARY (NOT MORE THAN 1,000 WORDS).

Please specify:

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

(2) With evidence that, if relevant, the procedure to be adopted complies with any the standards set out in the NH MRC statement on Human Experimentation and supplementary notes 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
First Floor C Block
189 Royal Street
EAST PERTH WA 6004

Telephone (09) 222 4260
Fax (09) 222 4236