



Reproductive Technology Council

INFORMATION FOR CLINICS ON THE PROCLAMATION OF THE RECENT AMENDMENTS TO THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991.

Background

Recent amendments to the *Human Reproductive Technology Act 1991* (HRT Act) will come into operation 1 December 2004. All the amendments contained in the *Human Reproductive Technology Amendment Act 2004* and the *Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004* will come into operation on that day. Those amendments will have significant impacts on your clinic's operations, which I first alerted you to in July 2004 following passage of the amendments.

Updated Directions to be given by the Commissioner of Health also commence on 1 December 2004. The revisions to the previously Gazetted Directions (1997) reflect the amendments to the HRT Act and otherwise incorporate earlier changes in policy which you have been aware of for some time, or reflect editing which has been carried out to make the Directions clearer.

The Directions may appear quite different but, other than as required by amendments to the HRT Act, there are no policy changes which you would be unaware of already.

This *Information for Clinics on the Proclamation of Recent Amendments to the HRT Act* (Information for Clinics) is to ensure that you are aware of the implications for your own clinic practices, as the required changes to your clinical practice or administration procedures must be in place by 1 December 2004.

Dealt with in this Information for Clinics are:

- Establishment of processes and standards for implementation of changes to the law relating to disclosure of identifying information in cases of donation of human reproductive material;
- Development and implementation of changes to embryo storage approval procedures;
- Development and approval of protocols for use of IVF to avoid transmission of infectious diseases such as HIV; and
- In relation to uses of embryos, an outline of appropriate responses to uses that are still to be overseen by the Reproductive Technology Council (Council) and uses that are to be overseen by the National Health and Medical Research Council (NHMRC) Licensing Committee.

If you have any queries or need any assistance, please contact staff of the Reproductive Technology Unit (RT Unit) or the Council.

Copies of the revised Directions will be sent to you as soon as they have been published in the *Government Gazette* and they will also be readily available from the State Law Publisher's web site as soon as they have been issued. An electronic version of the compiled HRT Act will also be available from the same web site, within a week of proclamation of the amendments.

You should now put in place revised protocols and patient information, as required to comply with the changes.

Please provide the Council with copies of your revisions by Friday 21 January 2005, in time for consideration at the February meeting of the Council (8 February 2005).

The establishment of approval processes for diagnostic testing of embryos (including pre-implantation genetic diagnosis (PGD)) is not covered in this document, as it is dealt with in full in a separate document.

A handwritten signature in black ink that reads "CA Michael". The signature is written in a cursive, flowing style.

**CA MICHAEL AO
CHAIR
Reproductive Technology Council
29 November 2004**

INFORMATION FOR CLINICS – AMENDMENTS TO THE HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991 EFFECTIVE FROM 1 DECEMBER 2004

1. Implementation of changes to the law relating to disclosure of identifying information in cases of donation of human reproductive material.

Amendments

Sections 49(2), (2a), (2b), (2c), (2d), (2e), (2f) of the *Human Reproductive Technology Act 1991* (HRT Act)

Revised Directions to be issued by the Commissioner of Health on 1 December 2004

Direction 8.5.

Effects

i) Donor offspring, upon reaching the age of 16, may be given identifying information about the donor.

Donor offspring, upon reaching the age of 16 and having undertaken approved counselling have the right to identifying information about the donor in circumstances where:

- The reproductive material was donated after the amendments come into effect (1 December 2004);
- The donation was made before 1 December 2004, but the Commissioner of Health is satisfied that there is clear evidence that the donor was informed that disclosure of identifying information was likely should there be a future change in the legislation; or
- The donation was made before 1 December 2004, but the donor on or after 1 December 2004 gave consent to the use.

ii) Parents who have used donated human reproductive material may consent on behalf of their minor children for sharing of identifying information.

Parents who have used donated human reproductive material to form their families may consent on their own behalf and on behalf of their minor children for sharing of identifying information about the donor, the recipients and the child where both the donor and recipient request this and in so far as it does not disclose the identity of any participant who has not given consent. This is to follow counselling (approved by the Commissioner of Health on advice from the Council) to address, in particular, what may be in the best interests of the child.

Implications and Actions for Licensees

i) Donations made after 1 December 2004.

For all donors who donate human reproductive material after 1 December 2004, licensees must ensure that the donors have consented to the material being used in the knowledge that the law provides that identifying information may be released to a

donor offspring aged 16 or over (Direction 4.2 refers to this). No donated human reproductive material should be accepted unless the donor is aware that identifying information will be provided to mature donor offspring if requested by the offspring and has consented to the future use of the material in this knowledge.

Donors should also be advised that once the donation has been used they will not have any opportunity to prevent the future release of identifying information to the donor offspring.

Licensees need to update patient information and consent forms explaining the impact of the amendments.

ii) Donations made prior to 1 December 2004 and used prior to 1 December 2004.

There will be no retrospective right to identifying information for offspring conceived using material donated before the commencement of the amendments, unless the donor had donated with knowledge that identifying information may be provided to offspring in the future. It is only where the donation was made with the knowledge that identifying information may be provided, or with the consent of these donors, that this information may be shared. In other words information may be provided in situations where there is clear evidence that the donor was aware at the time of the donation that information may later be provided to any resulting child.

This latter provision of information will be a matter of evidence, based on the records of the clinic at the time the donation was made. If a clinic considers that the donor had been provided with adequate information about possible future changes to the release of identifying information, the clinic should provide evidence of this to the Commissioner of Health for consideration. The Commissioner must be satisfied that the donor was adequately informed.

iii) Donations made prior to 1 December 2004 and not yet used.

Clinics with stored reproductive material donated prior to 1 December 2004 should attempt to contact the donors to seek a new consent to the use of the donated material. The new consent should either be given after 1 December 2004 (following appropriate information about the impact of the amendments), or should clearly indicate that the donor is aware that changes in the law will allow identifying information about the donor to be provided to a mature donor offspring.

Where the donor(s) cannot be found, or do not consent to the release of identifying information, their donated material should not be used again, except in circumstances established under new Direction 8.5 (b), (c) and (d).

The effect of the exceptions in these Directions 8.5 (b) and (c) is not that any donor offspring conceived using the donated material under these circumstance has a right to identifying information about the donor without the donor's consent. The donated material may be used under these exceptional circumstances, but any offspring conceived will not have a right to access to identifying information about the donor at age 16.

The circumstances where donated material can be used without the donor giving consent to the release of identifying information are:

- where an embryo was developed prior to 1 December 2004 using donated material and is in storage;

- where woman who has a child conceived using donated material prior to 1 December 2004 wishes to undergo a further donor treatment with the aim of having a full sibling to the existing donor child.

Material donated before 1 December 2004 may also be used where there was clear evidence that, at the time of the donation, the donor was advised about the possibility of changes in the law relating to provision of identifying information. In this case information can be provided to a mature donor offspring if requested. Before the donated material is used, the clinic must ensure the Commissioner of Health is satisfied about the adequacy of the information that was provided to the donor at the time of the donation.

Licensees need to update patient information and all relevant consent forms explaining the impact of the amendments.

iv) Sharing Identifying Information where children are under 16 years.

For children under 16 years each donor and recipient needs to consent to sharing identifying information and the parent needs to consent on behalf of the child. There must be “approved counselling” of all parties (which may include the child). In the interim the licensee can apply to the Commissioner of Health (via the Council) for approval concerning counselling and include the details of counselling proposed and by whom.

v) Counselling for New Donors and Recipients.

Counselling for new donors and recipients must explore issues concerning potential release of their identifying information to a donor offspring aged 16 or over.

2. Embryo storage approval procedures.

Amendments

Sections 3, 24, 28A, 53W(2)(a)(i,) of the HRT Act.

Revised Directions to be issued by the Commissioner of Health on 1 December 2004

Part 6

Effects

These amendments have significant implications relating to the storage of embryos, in relation to both the duration of permitted storage, persons who may apply for any extension to this and the removal of embryos from storage at expiry of permitted storage.

Implications and Actions for Licensees:

i) The maximum period of allowed storage of an embryo or an egg undergoing fertilisation is now 10 years. This amendment applies to all embryos regardless of when they were created. It remains unlawful for a licensee to store an embryo beyond its permitted storage period. Where embryos have already been extended by form 8 or 9 beyond 10 years, their storage term expires on the date specified by Council in the most recent extension.

ii) On the written application of an eligible person the Council may, if it considers there are special reasons in a particular case, grant an extension to permitted storage. Patients may apply for extension to the storage period of their own embryos, through the revised Form 8 application set out in the revised Directions, and Council will consider these on a case-by-case basis.

Other than where embryos have been donated for a use requiring a licence from the NHMRC (eg embryos donated for research), after 1 December 2004 clinics will no longer be able to apply for extension of the storage limit for patients using Form 9s.

iii) A licensee may allow an embryo to succumb without being subject to liability if the permitted storage period has ended and no application for extension is made, as long as they have taken reasonable steps *three months* before the end of the storage period to notify each person for whom an embryo is being stored that the storage period is coming to an end. (S 24(3) and (4)).

Council remains unable to approve applications to extend storage after expiry of the approved storage limit.

Changes to patient information and clinic protocols/ administrative processes are required.

3. Use of IVF to avoid transmission of infectious diseases such as HIV.

Amendments

Section 23(a)(ii) of the HRT Act

Effects

This amendment means IVF treatment can now be carried out where it would benefit a couple or woman whose child would otherwise be likely to be affected by a disease other than a genetic disease (eg an infectious disease such as HIV or Hepatitis)

Implications and Actions for Licensees:

Licensees may choose to introduce new practices to treat these eligible patients with IVF (or AIH) to avoid transmission of an infectious disease, such as HIV. At this stage, Council considers the protocols used for infection control and sperm washing to be “innovative procedures”. A clinic proposing to offer these treatments should make an appropriate application to the Council for approval prior to commencement.

Therefore, when applying for approval to carry out IVF, ICSI or IUI to avoid transmission of an infectious disease such as HIV the following need to be demonstrated:

- The reason for wanting to introduce the procedure;
- If the procedure is to be used on specific groups of patients the criteria for inclusion;
- Details on whether the procedure is used in other reputable clinics (nationally or internationally);
- Whether the procedure is expected to be successful in the clinic (eg training of staff to undertake the procedure);
- Safety and Effectiveness of the procedure based on research reports in the internationally peer-reviewed literature;
- Any risks of the procedure and outcomes.

4. The interface between uses of embryos that are still to be overseen by the Council and uses of embryos that are to be overseen by the NHMRC Licensing Committee

Amendments

Sections 53T(1) ('proper consent'); 53T(2); 53W (2) and (4) of the HRT Act.

Revised Directions to be issued by the Commissioner of Health on 1 December 2004

Revised Directions 4.3, 3.8 – 3.10.

Effects

Embryos that are no longer required for the treatment of the persons for whom they were created may be determined by those persons to be "excess ART embryos".

All uses of excess ART embryos, other than certain 'exempt uses' that are defined in section 53W of the HRT Act (and set out below) require an NHMRC Licence.

Implications and Actions for Licensees:

- i) A licensee wishing to use an excess ART embryo for any purpose other than an exempt use should contact the NHMRC Licensing Committee for guidance on procedures for applying for a licence for that use.

Revised Directions 4.3, 3.8, 3.9 and 3.10, set out details of the requirements for consent to donation of excess ART embryos for research..

- ii) All uses of embryos within clinical practice and all 'exempt uses' are to be overseen by the Council. The Council will oversee the following 'exempt uses' of excess ART embryos:
 - Storage; removal from storage; and allowing to succumb;
(See section 2 above for more information on storage)
 - Transport;
 - Observation only;
 - Some diagnostic procedures;
 - Donation to another couple for treatment.

Persons eligible to apply for extensions to storage of excess ART embryos will depend on whether these are to be donated for another couple or research. This is covered in more detail in part 2 herein (Embryo storage).

Where a diagnostic procedure on an embryo is to be carried out the requirements and approval processes will differ depending on whether the embryo to be tested is an excess ART embryo or not. This is covered in detail in separate information already provided to clinics by the Council: (*Approval for diagnostic testing of embryos: Advice to clinics*, November 2004).