Reproductive Technology Council

NOTICE TO LICENSEES

TO: **LICENSEES UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* (the HRT Act)**

FROM: **Professor Con Michael AO**
Chair
Reproductive Technology Council

DATE: **24 February 2006**

RE: **COOLING OFF PERIOD FOR COUNSELLING IN CASES OF KNOWN OOCYTE DONATION**

Background

At it's meeting on 13 December 2005, the Reproductive Technology Council (Council) considered the recommendation of the Counselling Committee to reduce the cooling off period for counselling for cases of known oocyte donation to a minimum of three months.

This recommendation was based on consultation with consumers and clinic counsellors. It is becoming evident that with the revised and more rigorous requirements of the RTAC Code of Practice fewer women are able to undertake fresh embryo transfer. Therefore for those women requiring known egg donors they may have to wait up to 12 months before being able to progress their treatment due to the 6 month cooling off period for counselling (Part 2, Schedule 4 to the HRT Act) (see **attachment 1**) and the RTAC requirement for a 180 day quarantine period for screening purposes. Whereas in the case of known sperm donation, the cooling off period for counselling can occur concurrently with the RTAC requirement of the 180 day quarantine period. Council understands this wait may be of concern to some patients, particularly as there is also an increasing trend of advanced maternal age.

Recommendation

Council has agreed with the Committee's recommendation that the cooling off period for counselling in cases of known oocyte donation be reduced to a minimum of three (3) months to be applied in addition to the RTAC requirement for a 180 days quarantine period in relation to a fertilised oocyte (RTAC Code of Practice – 9.9) (see **attachment 2**).

Please note that this variation to Part 2, Schedule 4 of the Directions under the HRT Act applies only to known egg donation and NOT known sperm donation.

Con. Michael

Professor Con Michael AO, Chair Reproductive Technology Council

Attachment 1

HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991

DIRECTIONS

Given by the Commissioner of Health to set the standards of practice under the *Human Reproductive Technology Act 1991* on the advice of the WA Reproductive Technology Council

SCHEDULE 4

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

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

- Counselling must be provided by an approved counsellor;

- Counselling should preferably be provided before the medical assessment of the participants;

- Information that has been approved by the Council in accordance with the Directions should be provided to each participant;

- Initial counselling should include a minimum of three hours counselling in three individual sessions during which the recipient (and spouse or de-facto spouse, if any) and donor (and spouse or de-facto spouse, if any) should be seen separately and then together;

- A six month cooling off period should be allowed following the completion of initial counselling before the donated material is used in an artificial fertilisation procedure;

- At the end of the cooling of period each participant should have further contact with the approved counselor to ensure her/his continued willingness to proceed;

- An exit interview with an approved counselor must be provided for participants who are not proceeding with the program;

- All counseling should be face to face unless this is very difficult to arrange. If face to face counselling cannot be arranged the approved counsellor may conduct the counselling by phone or video-link;

- Counselling of a person who is not resident in WA may be provided by an interstate or overseas counsellor who is a member of the Australian and New Zealand Infertility Counsellors Association (ANZICA) (or equivalent);

- The costs of counselling would generally be borne by recipients.

CODE OF PRACTICE FOR ASSISTED REPRODUCTIVE TECHNOLOGY UNITS
Fertility Society Of Australia
Reproductive Technology Accreditation Committee
(revised February 2005)

Testing of donors and samples

9.9 Donor screening tests

It is recommended that mandatory screening tests for donor suitability be carried out at a NATA/IANZ-accredited laboratory. Mandatory tests are the minimum tests required for the release for supply of gametes/embryos, and are determined by the TGA in consultation with industry. The following mandatory tests may be changed or extended as required and determined by the TGA:

- human immunodeficiency virus (HIV) types 1 and 2
- hepatitis C virus
- hepatitis B virus
- human T-cell lymphotropic virus type 1
- syphilis
- microbiological contamination testing.

There must be a documented procedure for the taking of laboratory samples for medical screening of donors. Blood and semen samples for laboratory testing of donors must be taken within an appropriate time of the first donation. Documented procedures must detail the laboratory screening tests required, and the rationale for inclusion, before gametes/embryos can be released for supply.

Documentation should include the acceptance and rejection criteria for individual screening tests. The documented procedure must include the requirement that sperm supplied by a donor is able to be cryostored for 180 days. At the end of this quarantine period, the donor is required to be retested for HIV, hepatitis B and hepatitis C. Where any of these tests is confirmed as positive, the sperm is to be discarded unless specific consent for use by the recipient has been obtained.

In the case of donated oocytes, RTAC recommends that the documented procedure should allow for the oocytes to be fertilised and the embryos cryostored for 180 days. At the end of this quarantine period, the donor is required to be retested for HIV, hepatitis B and hepatitis C. Where any of these tests is confirmed as positive, the embryos are to be discarded unless specific consent for use by the recipient has been obtained.

Oocyte donation with embryo formation followed by fresh embryo transfer may be considered appropriate by an ART unit. The documented procedure must include a risk assessment for infectious disease transmission (particularly HIV). The documentation must include the requirement that recipients are to be informed before signing the consent form of the risks of using fresh embryo transfer (even when the donor is known to them). Where screening protocols change during the life of the gametes/embryos in storage, the donor is required to be retested with the new screening test protocol.

Where the gamete/embryo specifications require mandatory tests additional to those noted above before release for supply, records must demonstrate that the gametes/embryos have met the requirements for these additional tests. Permanent records of screening test results must be retained.