



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: Effective from 16 May 2006

RE: COOLING OFF PERIOD FOR PSYCHO SOCIAL PREPARATION IN CASES OF KNOWN EMBRYO DONATION

Background

At its meeting on 16 May 2006, the Reproductive Technology Council (Council) considered the “cooling off” period for psycho-social/counselling preparation in cases of known embryo donation. In reaching its decision Council took into account legal advice and the discussion held at its meeting of 13 December 2005 where the Counselling Committee recommended the reduction of the cooling off period for cases of known oocyte donation to a minimum of three months.

Members recognised that in embryo donation people may be more attached to their embryos (than in gamete donation), especially if they have had children from the same set of embryos. However, it was acknowledged that in the decision-making concerning the future of stored embryos participants often deliberated for a longer period of time about their options and the consequences of each option before deciding to donate. Additionally, it was noted that recipients seeking donated embryos tended to be older and that it was preferable for them to undergo the treatment as soon as possible.

Therefore the Council agreed that for those participants deciding to undergo IVF treatment with known donor embryos they are required to have a minimum of three (3) months cooling off period following the psycho-social preparation/counselling before proceeding with treatment. The RTAC requirement for the 180 day quarantine period for screening purposes still applies. However, Council accepted that in the majority of cases of embryo donation the quarantine period would have been met, as generally embryos would have been in storage for over 6 months.

Recommendation

Council has agreed that the cooling off period for psycho-social preparation/counselling in cases of known embryo donation (**Part 2, Schedule 4 to the HRT Act**) (see attachment 1) be reduced to a minimum of three (3) months. This will be in addition to the RTAC requirement for a 180 days quarantine period for screening purposes. (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 and embryo donation and NOT known sperm donation.

Professor Con Michael AO, Chair Reproductive Technology Council

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 off 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.