



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: 8 May 2006

RE: OOCYTE CRYOPRESERVATION

Background

The Reproductive Technology Council (Council) gave consideration to this matter at its meeting on 11 April 2006 following advice received concerning this matter.

Collection and Storage of Oocytes

Legal advice received indicates that the collection and storage of mature oocytes through oocyte cryopreservation, is considered a storage procedure under the *Human Reproductive Technology Act 1991* (the HRT Act). Therefore, it is subject to the general provisions under the HRT Act and Directions, such as consents and information giving as well as the specific requirements of gamete storage in Part 6 of the Directions. The eligibility criteria under Section 23 of the HRT Act are **not** applicable to storage procedures.

Oocyte Cryopreservation as an Innovative Procedure

At its meeting, Council also determined that the oocyte cryopreservation procedure meets the criteria for an innovative procedure given the associated technology is relatively new and patients would need to be appropriately informed of the risks and benefits. In accordance with Direction 4.1 information to be provided prior to effective consent must be in a written form approved by Council and Direction 3.7, requires that the licensee must ensure that participant(s) give a separate consent to each innovative procedure, diagnostic procedure or research that is subject to approval of Council.

Licensees of ART clinics will therefore require specific approval from Council for this innovative procedure firstly to carry out this procedure and secondly at the time of intended use of the stored oocytes. This is in accordance with Section 20 of the HRT Act and Section 9 of the Directions.

Future Use

In terms of the potential future uses of these cryopreserved oocytes, in cases where the oocytes are used for ART treatment, at the time of the IVF procedure, participants will need to meet the eligibility criteria for IVF treatment (under Section 23 of the HRT Act). For other potential uses of cryopreserved oocytes, such as nuclear transfer, it is recommended that licensees consult with Council prior to intended use to identify whether the specific use is subject to any legislative requirements at that time. For example, currently nuclear transfer (to create a clone) is **not** permitted under the Commonwealth *Prohibition of Human Cloning Act 2002*.

Requirements

Licensees of ART clinics will require specific approval from Council:

- firstly to carry out this procedure and
- secondly at the time of intended use of the stored oocytes.

Licensees must also submit to Council the relevant proposal, ethics approval, consent forms and patient information for Council approval.



Professor Con Michael AO, Chair Reproductive Technology Council