



NOTICE TO LICENSEES

TO: Licensees under the *Human Reproductive Technology Act 1991* (HRT Act)
FROM: Professor Con Michael AO
Chair, Reproductive Technology Council
DATE: 25 May 2006
RE: Direction 7.7- IVF treatment to avoid the transmission of an infectious disease

Background

The Reproductive Technology Council (Council) gave consideration to the process for approvals of applications under Direction 7.7 at its meeting on 16 May 2006. Direction 7.7 states: *The licensee must ensure that an IVF procedure directed at reducing the risk of transmission of an infectious disease, such as HIV or hepatitis, is not undertaken without the prior approval of the Council.*

Recommendation

The Council determined that the requirement for application would vary depending on the mode of transmission of a disease.

Viruses not transmitted through reproductive bodily fluids

For viruses not typically transmitted through sexual intercourse, eg Hepatitis C, if clinics standard protocols for infection control are adequate general approval is granted to treat these patients with IVF and therefore an application under Direction 7.7 is not required.

Viruses transmitted through reproductive bodily fluids

For viruses transmitted through sexual intercourse, including Hepatitis B and HIV, an application under Direction 7.7 is required. Based on consideration of this application Council will determine whether general approval or specific approval (as an Innovative Practice) is required. This applies regardless of whether the IVF procedure is being used to reduce the risk of transmission of the infectious disease or not.

As part of the application the following information should be supplied:

- Risks of transmission of the infectious disease to the embryo
- Protocol on infection control to be used
- Patient information and consent forms applicable to the case

Clinics who have already been granted specific approval as an Innovative Procedure to undertake treatment of patients at risk of transmitting a specific infectious disease are not required to re-apply.

Professor Con Michael AO, Chair Reproductive Technology Council
