FORM 1: APPLICATION FORM FOR SPECIFIC APPROVAL OF AN INNOVATIVE LABORATORY OR CLINICAL PROCEDURE

Directions 9.4 and 9.5

Name of Licensee

Licence Supervisor

(full name)

Address

Tel:

Fax:

Human Research Ethics Committee Chairperson (Name)

New/modified procedure for which SPECIFIC approval is sought:

Reference No: (for office use only)

The Reproductive Technology Council has granted its Specific Approval to this innovative practice.

General conditions

Unless any of the following general conditions are struck out, this Approval is subject to the following general conditions, and any other condition specified:

The licensee is to-

i) provide the Council with a progress report on the use of this procedure annually, at the time of annual reporting;

ii) notify the Council if the procedure is no longer used, with a full report of the findings; and

iii) monitor the literature and other available information about the use of similar procedures elsewhere, and ensure that Council is notified as soon as practicable of any relevant adverse findings.

Specific conditions (to be specified, if any)

Issued (date):

Signed: (Chairperson, Reproductive Technology Council)

DETAILS OF PROPOSAL FOR SPECIFIC APPROVAL OF AN INNOVATIVE PROCEDURE

Before completing please read the sections of the Directions relevant to research and innovative practices under WA's Human Reproductive Technology Act 1991.

SUMMARY (NOT MORE THAN 1,000 WORDS).

Please specify:

(1) Whether HREC approval has been sought and, if so, provide any comments on the proposal by the relevant HREC.

(2) With evidence that, if relevant, the procedure to be adopted complies with any the standards set out in the NHMRCs 'National Statement on Ethical Conduct of Research Involving Humans' and 'Ethical guidelines on ART' and any relevant professional guidelines.

(3) With evidence and details, whether the procedure proposed -

is used in other reputable, nationally or internationally recognised clinics;

is reported in international peer-reviewed literature indicative of safe and successful outcome, based on good research;

is expected to be successful in the local clinic;

is expected to be safe for any person likely to be affected by it, in the short and long term.

(4) Full details of the proposed change or addition, including a copy of the information to be provided to participants to assist in their informed consent to the procedure.

(5) Supporting documentation, references.

Please return to:

The Executive Officer
The WA Reproductive Technology Council
Licensing and Accreditation Regulatory Unit
Department of Health
189 Royal Street, East Perth WESTERN AUSTRALIA 6004
Email: LARUReception@health.wa.gov.au