FORM 2: APPLICATION FORM FOR SPECIFIC APPROVAL OF RESEARCH HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991 Directions 9.6 and 9.7

Name of License

Licence Supervisor

(full name)

Address

Tel:

Fax:

Human Research Ethics Committee

Chairperson (Name)

Title of research project for which specific approval of Council is sought -

Date of application:

Reference No:

(for office use only)

The Reproductive Technology Council has granted its Specific Approval to this research. 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 project annually, at the time of annual reporting;
- ii) notify the Council if the research is terminated, with a full report of the findings; and
- iii) monitor the literature and other available information about similar research 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):

(Chairperson, Reproductive Technology Council)

Signed:

DETAILS OF PROPOSAL TO CARRY OUT RESEARCH UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT* 1991

Before completing please read Directions 9.6 and 9.7 SUMMARY (NOT MORE THAN 1,000 WORDS).

Please specify:

- (1) Whether research is to be carried out by the licensee or facilitated by them, and if so who will carry it out.
- (2) What is the subject of the research:
 - (a) participant(s);
 - (b) sperm or eggs intended for use in an artificial fertilisation procedure;
 - (c) eggs undergoing fertilisation; or
 - (d) embryos

(Please note that the Council may only approve research involving human embryos that are intended for use in the reproductive technology treatment of a woman (s.14(2a)) or use of excess ART embryos referred to in s.53W(2)(b) or (f) of the Act (ie observation only, or a use prescribed in Commonwealth regulations for the purposes of s.10(2)(f) of the Commonwealth Research Involving Human Embryos Act 2002.

A licence from the NHMRC is required for any use of an excess ART embryo that is not an 'exempt use').

- (3) Whether HREC approval has been sought and if so, provide comments made on the proposal by the relevant HREC.
- (4) With evidence that the procedure to be adopted complies with the standards set out in the NHMRCs 'National Statement on Ethical Conduct of Research Involving Humans' and 'Ethical guidelines on ART'.
- (5) If the research is embryo research of the type that the Council may approve, give evidence supporting that-
 - (a) the embryo is intended for use in the reproductive technology treatment of a woman and existing scientific and medical knowledge indicates that the research is unlikely to leave the embryo unfit to be implanted in the body of a woman (s.14(2a)(a)); or
 - (b) the proposed research or use of an excess ART embryo consists of a use referred to in s.53W(2)(b) or (f) (observation only or a use prescribed in Commonwealth regulations for the purposes of s.10(2)(f) of the Commonwealth Research Involving Human Embryos Act 2002).
- (6) Full details of the proposal.
- (7) Supporting Documentation, references.

Please return to :

The Executive Officer The WA Reproductive Technology Council Department of Health 189 Royal Street, East Perth WESTERN AUSTRALIA 6004 Email: <u>rtu@health.wa.gov.au</u>