**APPLICATION FORM FOR APPROVAL UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991* (HRT ACT) FOR A DIAGNOSTIC PROCEDURE TO BE CARRIED OUT UPON OR WITH AN EMBRYO**

Name of Licensee:

Licence Supervisor:

(Full name)

PGD Coordinator:

(Full name)

Address:

Tel:

Fax:

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Is approval being sought to undertake **aneuploidy screening** prior to implantation?

[ ]  yes\* [ ]  no

\*If yes please complete Part A & Part B.

Is approval being sought to undertake **genetic testing for a specified condition** prior to implantation?

[ ]  yes\* [ ]  no

\*If yes please complete Part A & Part C.

Is approval being sought to undertake **diagnostic testing on an excess ART** embryo?

[ ]  yes\* [ ]  no

\*If yes please complete Part D.

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#### For office use only

Reference No:

Issued:       (Date):

Signed:

(Chairman, Reproductive Technology Council)

**INSTRUCTIONS:**

* This form is available electronically on the Reproductive Technology Council website at [www.rtc.org.au](http://www.rtc.org.au) under ‘Information for Clinics > Forms’.
* The information requested may be printed or typed in the shaded boxes or provided as attachments.
* Do not include patient identifying information in the application.
* The application must be submitted:
* by e-mail to pgd@health.wa.gov.au

**PART A: APPROVAL OF TECHNICAL PROCEDURES.**

Item 1: BIOPSY PROCEDURES

Do you have specific approval from the Reproductive Technology Council to undertake the relevant embryo biopsy procedures?

[ ]  yes [ ]  no\*

\*If no please provide details of the procedures intended to be used by reference to the following standards.

* Laboratories must be licensed under the HRT Act and maintain accreditation by the Reproductive Technology Accreditation Committee (RTAC).
* Laboratories must participate in a QA program recognised by RTAC/NATA.
* The biopsy procedure to include setting up of microtools on an inverted microscope, placing oocyte/embryo in microdroplets for the procedure, removal of cell/polar body, placing cell into appropriate transport container.
* HREC approval for the procedure(s) to be used.
* The biopsy techniques to be used may be acid Tyrode’s or laser as approved by the Council.
* Biopsy may be in the form of polar body biopsy, embryo biopsy (at day 3) or blastocyst as approved by the Council.
* Staff performing the biopsy must have demonstrated competency in:

 ⮚ the proposed biopsy technique;

 ⮚ placing the cell(s) in transport vessel, in the case of single gene defects; and

 ⮚ fixing of cell(s) on a slide in the case of chromosome analysis.

Please provide attachments if necessary and note the attachment numbers

in this box.

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Item 2: EXTENDED BLASTOCYST CULTURE

 Are you intending to use extended blastocyst culture?

[ ]  yes\* [ ]  no

 \*If yes do you have specific approval from the Reproductive Technology Council to undertake extended blastocyst culture?

 [ ]  yes [ ]  no\*

\*If no please provide details of the procedure intended to be used as required for a standard application for specific approval.

Please provide attachments if necessary and note the attachment numbers

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# ---------------------------------------------------end of Part A-----------------------------------------------

# PART B: APPROVAL TO UNDERTAKE ANEUPLOIDY SCREENING

Item 1: Criteria to be applied to undertake aneuploidy screening.

Are you seeking approval for screening against the following standard criteria?

* The woman or couple is eligible for IVF under the HRT Act; and
* women over 35 years of age providing eggs; or
* women with 2 or more miscarriages; or
* women with >2 failed IVF attempts where embryos have been transferred; or
* women referred by a clinical geneticist with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements.

 [ ]  yes [ ]  no\*

\*If no please provide details of the criteria to be applied and the scientific or medical justification for the criteria.

Please provide attachments if necessary and note the attachment numbers in this box.

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Item 2: GENETIC TESTING

 Please provide details of the proposed testing and the testing facility to be used by reference to the following standards.

* Laboratories must be accredited by the National Association of Testing Authorities (NATA), (or working towards accreditation within the NATA 3 year cycle) to carry out the type of testing being undertaken.
* Laboratories must meet all relevant NATA and National Pathology Accreditation Advisory Council (NPAAC) requirements for testing.
* Laboratories must participate in an accredited quality assurance program (QAP) for FISH, preferably with a PGD component, which may be offshore.
* Laboratories should adhere to the standards set by the European Society for Reproduction and Embryology (ESHRE) (see ESHRE website) unless otherwise approved by the Council.
* All PGD testing should confirm with the Australian standard for PGD-AS (if any).

Please provide attachments if necessary and note the attachment numbers

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Item 3: Details of information and counselling to be provided in respect of screening.

 Please provide attachments if necessary and note the attachment numbers in this box.

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**---------------------------------------------------end of Part B-----------------------------------------------**

**PART C: APPROVAL TO UNDERTAKE TESTING FOR A SPECIFIC CONDITION**

Item 1: Details of condition to be tested for

 Does the application have the support of a clinical geneticist (or genetic counsellor if directed as per s 2.4.1 paragraph 43) who has assessed the risk and seriousness of the condition to be tested for?

 [ ]  yes [ ]  no

Please attach a report from a clinical geneticist addressing the following questions as relevant:

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| Areas to be addressed | Criteria |
| Is there a significant risk of a serious genetic abnormality or disease in the context of the family that is requesting the testing? | E |
| What is the genetic abnormality or disease that is to be tested for? | E |
| What experience with, and attitude to, the abnormality or disease does the family requesting the testing have? | E |
| What factors indicate that there is a risk that the embryo will be affected by the genetic abnormality or disease? | E |
| What is the level of impairment to body functions and structures that is usually associated with the abnormality or disease? | E |
| What difficulties would a person with the abnormality or disease be expected to have in participating in activities such as learning and applying knowledge, communication, mobility, self-care, employment and community, social and civic life? | E |
| What is the level of support that would be required by a person who has the abnormality or disease? | D |
| What are the prospects for new and longer-term treatments and interventions for the condition? | D |
| What is the capacity of the family who are requesting the testing to provide the level of support required by a child with the abnormality or disease? | D |
| What clinical genetic and diagnostic data are to be used in the testing procedure? | D |
| What other testing options are available? | D |
| What level of information will be possible from the test, in terms of interpretation, sensitivity and specificity (includes error)? | D |
| Has the person requesting the testing been provided with counselling about the potential impact of testing and contact information for other persons or organisations that have experience with the condition? | D |

Criteria: E = Essential D = Desirable

Item 2: GENETIC TESTING

Please provide details of the proposed testing and the testing facility to be used by reference to the following standards.

* Laboratories must be NATA accredited (or working towards accreditation within the NATA 3 year cycle) to carry out the type of testing being undertaken.
* Laboratories must meet all relevant NATA and NPAAC requirements for testing.
* Laboratories must participate in an accredited QAP for molecular genetics, preferably with a PGD component, which may be offshore.
* Laboratories should adhere to the standards set by the European Society for Reproduction and Embryology (ESHRE) (see .ESHRE website) unless otherwise approved by the Council.
* All PGD testing should conform with the Australian standard for PGD-by molecular techniques (if any).
* Laboratories must demonstrate competency in transfer of cell(s)/polar body(s) to a testing laboratory in a state capable of being analysed and free from contaminants.
* Where the cell(s) are to be couriered interstate/overseas for PGD analysis, laboratories must demonstrate that the proposed courier system is safe, accurate and efficient (including quick ‘turn-around’).

Please provide attachments if necessary and note the attachment numbers

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Item 3: Additional statement from the person requesting testing (optional)

 Please provide attachments if necessary and note the attachment numbers

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**---------------------------------------------------end of Part C-----------------------------------------------**

PART D: APPROVAL FOR DIAGNOSTIC PROCEDURE ON EXCESS ART EMBRYOS

Item 1: Detail of procedure to be carried out.

 Please provide attachments if necessary and note the attachment numbers

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Item 2: Criteria by which an embryo will be identified as unfit for implantation.

Please provide attachments if necessary and note the attachment numbers

in this box.

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Item 3: Details of how the procedure will benefit the woman for whom it is undertaken.

 Please provide attachments if necessary and note the attachment numbers

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Item 4: Is approval being sought for the procedure to be part of general clinical practice?

 [ ]  yes\* [ ]  no

 \*If yes please provide a copy of the relevant sections of the clinical protocol.

 Please provide attachments if necessary and note the attachment numbers

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**-------------------------------------------------end of application---------------------------------------------**