Application: Embryo research licence for embryo biopsy training using excess ART embryos

When completing this application form, please refer to the *Instructions: Embryo research licence application for embryo biopsy training using excess ART embryos* (on the NHMRC website)

Section 1 – Applicant information

1.1 Applicant Information

1.1.1. Organisation[1]	
Organisation name	
Street address	
Postal address	
ABN or ACN	

1.1.2. Organisation Representative[2]	
Title	
Given name	
Surname	
Position	
Contact number	
Email address	

[1] Applicant Organisation: A legal entity (not an individual researcher or ART clinician). The organisation will be the licence holder and will be responsible for ensuring compliance with licence conditions.

[2] Organisation Representative: A person with legal authority to sign the application on behalf of the organisation (for example, the Scientific Director of an ART Clinic)

1.1.3. Contact person for licence application[3]	
Title	
Given name	
Surname	
Position	
Contact number	
Email address	

1.2 Proposed Authorised Persons

1.2.1 – Principal Supervisor

1.2.1.1 Principal Supervisor[4]	
Title	
Given name	
Surname	
Position	
Contact number	
Email address	
Role in proposed activity *Describe the person's role in the proposed activity, including information about whether the person will be creating or using embryos or using human cells.* *Attach a full curriculum vitae. The CV should indicate relevant embryology or other skills.*	
Attachment number for CV	

[3] Contact Person: Person familiar with the application who can be contacted with queries relating to the application. For example, the organisation representative (1.1.2), the Principal Supervisor (1.2.1) or another staff member.

[4] Principal Supervisor: Authorised person who will oversee the proposed activity. The person nominated as the Principal Supervisor must have technical insight into all aspects of the proposed training activity and sufficient authority to fulfil the role described above. This person could be the chief scientist or director of clinical sciences in the ART clinic.

1.2.1.2 Joint[5] or Alternate[6] Principal Supervisor (if applicable)	
Role	Please select one
Title	
Given name	
Surname	
Position	
Contact number	
Email address	
Role in proposed activity *Describe the person's role in the proposed activity, including information about whether the person will be creating or using embryos or using human cells.* ***Note that the Principal Supervisor (or an alternate Principal Supervisor, if any) must oversee all blastocyst biopsies conducted under this licence.*** *Attach a full curriculum vitae. The CV should indicate relevant embryology or other skills.*	
Attachment number for CV	

[5] A joint Principal Supervisor is considered by ERLC to have shared responsibility for the licensed activity at all times

[6] An alternate Principal Supervisor takes responsibility for the licensed activity in the absence of the Principal Supervisor.

1.2.2 Staff who will use excess ART embryos *(duplicate this section as required)*	
Title	
Given name	
Surname	
Position	
Contact number	
Email address	
Role on licence (please tick one and complete relevant fields):	
☐ Trainer (if different from Principal Supervisor)	Role in proposed activity *Describe the person's role in the proposed activity, including information about whether the person will be creating or using embryos or using human cells. Attach a brief curriculum vitae indicating relevant embryology or other skills.*
	Attachment number for CV
☐ Trainee	Justification for training the embryologist in embryo biopsy *A one sentence justification for training the embryologist in embryo biopsy (for example, operational requirements due to staff movements; increasing demand for Pre-implantation Genetic Testing).*

Competency	
ERLC requires that each authorised person has demonstrated skill in the micromanipulation of animal and/or human gametes and embryos before requesting training under this licence. **Please select one:**	
☐	The Principal Supervisor confirms that the proposed authorised person is **COMPETENT** in the micromanipulation of animal and/or human gametes and embryos.
☐	The Principal Supervisor confirms that the proposed authorised person is **NOT COMPETENT** in the micromanipulation of animal and/or human gametes and embryos.

1.3 Specified Sites

1.3.1 Site(s) of the proposed activity (duplicate this section if required)	
Building name	
Level or room number	
Street number and name	
Suburb	
State and postcode	

1.3.2 Site(s) of records (other than patient records) associated with the proposed activity (duplicate this section if required)	
Building name	
Level or room number	
Street number and name	
Suburb	
State and postcode	

1.3.3 Site(s) of patient records (including original consent document) associated with the proposed activity (duplicate this section if required)	
Building name	
Level or room number	
Street number and name	
Suburb	
State and postcode	

Section 2 – Project Description

This simplified application form may only be used by applicants wishing to apply for a licence to use excess ART embryos for training in embryo biopsy.

2.1 Title of proposed use	
The standard title for a licence to use excess ART embryos for training in embryo biopsy is: **'Use of excess ART embryos for blastocyst-stage biopsy training'** Please check one option below:	
☐	The standard title is appropriate for the proposed licence.
☐	The title of proposed use is not appropriate for the proposed licence *(please provide alternative title and justification):*

2.2 Short description of the proposed use of excess ART embryos	
The standard description of activity authorised by the licence and goals of the activity is: **"This licence authorises trainee embryologists to use excess assisted reproductive technology (ART) embryos to attain proficiency in blastocyst-stage embryo biopsy. The embryos to be used under this licence are frozen embryos which have been declared to be excess to the reproductive needs of the responsible people concerned. The goals of the licensed activity are to allow embryologists to achieve competence in the technique of blastocyst-stage embryo biopsy through the use of limited numbers of excess ART embryos."** Please check one option below:	
☐	The standard description of proposed use above is appropriate for the proposed licence.
☐	The title of proposed use is not appropriate for the proposed licence *(please provide alternative title and justification)*:

2.3 Proposed duration of licensed activity	
Select the preferred duration for the licence (from the licence issue date) and provide a brief explanation for the selection:	
☐	6 months
☐	12 months
☐	24 months
☐	36 months
Brief explanation for proposed duration:	

2.4 ART clinic(s) from which the excess ART embryos will be obtained	
Provide details for each clinic which will provide excess ART embryos to be used in the proposed training activity (duplicate this section if required):	
Organisation name	
Street address	
Contact name	
Position	
Telephone number	
Email address	

2.5 Survival rate for embryos thawed at relevant ART clinic	
*ERLC has determined that under this licence type, each trainee **may use up to 20 excess ART embryos** during their training in embryo biopsy. Not all embryos survive thawing or reach the developmental stage required and embryos used for biopsy training must be live embryos. Provide information about the expected survival rate for thawed embryos to assist ERLC in determining the number of excess ART embryos to be removed from storage and authorised for use in training. This information must be specific to each clinic(s) listed at section 2.6.*	
Attachment number (if required)	

Section 3 – Proper consent protocols

To issue a licence, ERLC must be satisfied that appropriate protocols are in place to enable proper consent to be obtained before an excess ART embryo or human egg is used, or other embryo is created or used.

When developing the consent process and documents, please consult:

- *Research Involving Human Embryos Act 2002*
- *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (ART Guidelines)
- *National Statement on Ethical Conduct in Human Research* (the National Statement), and
- any other relevant advice or guidelines issued by the NHMRC.

The *Consent checklist for Licensed Activities using excess ART embryos* available on the NHMRC website will assist applicants to develop consent processes for the use of excess ART embryos that are in accordance with the regulations and guidelines noted above. Please refer to the checklist on the NHMRC website at www.nhmrc.gov.au/research-policy/embryo-research-licensing/information-applicants before completing section 3.

3.1 Overview of proper consent process
Provide a description and a flowchart which details the order and timing of the provision to responsible persons of the participant information and consent forms (see section 3.2). Describe how you will ensure that you notify ERLC that proper consent has been obtained before each excess embryo or human egg is used under the licence (see RIHE Act s24(1)). Provide attachments and note the attachment numbers in this box.

Attachment number/s	

3.2 Tracking system	
Describe the tracking system that will be used to identify the excess ART embryos or human eggs used, or other embryos created or used in the proposed activity. Maintenance of a tracking system that links individual embryos and eggs to a specific licence and responsible persons will be a condition of a licence granted and Embryo Licence Inspectors will audit the system during their inspections. Provide attachments if necessary.	
Attachment number/s (if required)	

3.3 Documents to be provided to obtain proper consent	
Attach copies of all documentation to be provided to research participants to obtain proper consent and note attachment numbers in this box. Do not attach any signed consent forms or forms containing personal information about donors.	
Attachment numbers:	

3.4 Payment of reasonable expenses[7]	
Specify the amount, if any, to be paid to research participants and/or donors and provide a justification for the level of reimbursement of reasonable expenses. Also provide details of any 'in-kind' benefits, discounts or gifts that participants and/or donors will be offered. Attach a copy of all documentation used and note attachment numbers in this box.	
Attachment number/s (if required)	

[7] Note that under section 21 of the *Prohibition of Human Cloning for Reproduction Act 2002*, giving or receiving benefits, or offering to give or receive benefits, in excess of reasonable expenses, is a serious offence punishable by imprisonment for up to 15 years.

Section 4 – Agreement to meet certain conditions

Please read section 4 and ensure you understand the conditions of a licence to use excess ART embryo for embryo biopsy training purposes. By signing section 6, you are agreeing to meet the conditions set out below.

4.1 Standard licence Conditions

I declare that the applicant organisation will meet all conditions that are specified in the document *Standard Conditions for General Licences* as currently published on www.nhmrc.gov.au/research-policy/embryo-research-licensing/database-licences-issued, as amended from time to time.

4.2 Special Conditions for licences to use excess ART embryos for embryo biopsy

I declare that the applicant organisation will meet the following conditions that will be included as Special Conditions in any licences issued for the use of excess ART embryos for embryo biopsy:

- A maximum of 20 suitable excess ART embryos may be used to train each trainee in the technique of embryo biopsy.
- Each embryo must be declared to be excess (refer section 9, *Research Involving Human Embryos Act 2002*) before proper consent is sought to use the excess ART embryo in the licensed training.
- A 'suitable' embryo is an excess ART embryo which has greater than 50% of its blastomeres intact immediately following thawing and at the stage when it will be used for training.
- The Principal Supervisor must confirm that before a trainee uses an excess human ART embryo for embryo biopsy training in accordance with this licence, the trainee:
  - (i) is named by ERLC as an 'authorised person' on this licence, and
  - (ii) has demonstrated skill in the micromanipulation of animal and/or human gametes.
- The licence holder must provide the following information to ERLC in addition to the reporting requirements specified in the Standard Conditions:
  - (i) the name of each authorised person who has received training (the trainee)
  - (ii) the site/s where each trainee has been trained
  - (iii) the number of excess ART embryos thawed and how may 'suitable embryos' have been used for training by each trainee, and
  - (iv) the outcomes of the training.

4.3 Monitoring compliance

I am aware that the conditions detailed at section 4.1 and 4.2 above will be included as conditions of any licence(s) issued and the Embryo Licence Inspectors will audit these practices and procedures during their inspections.

Section 5 – Human Research Ethics Committee Approval

The activity proposed in the application must be assessed and approved by a HREC that is constituted in accordance with, and acting in compliance with, the National Statement. For more information and a list of approved HRECs: www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees

5.1 Human Research Ethics Committee (HREC)	
Name of HREC	
Institution / Organisation	
HREC email	

5.2 HREC Consideration of Application

5.2.1 Date of HREC approval

5.2.2 HREC evaluation and approval/clearance	
Attach the HREC evaluation and approval/clearance of the proposed activity and indicate the attachment number here. Refer to the Instructions for completing this form when preparing the HREC evaluation statement that is required here.	
Attachment number	

Section 6 – Signatures

I declare that to the best of my knowledge, having made reasonable inquiries, the information herein is true and correct.

I declare that I understand and agree to the conditions set forth in section 4 of the application.

I understand that providing misleading information to NHMRC, deliberately or otherwise, is an offence under Commonwealth law.

6.1 ORGANISATION REPRESENTATIVE	
Signature	
Date	
Printed name	
Position	

6.2 PRINCIPAL SUPERVISOR *If joint or alternate Principal Supervisors are named at 1.2.1, each one should sign the form here. Duplicate the section as required.*	
Signature	
Date	
Printed name	
Position	

7. Index of Supporting Information

Attachment Number	Attachment Title