EMBRYO RESEARCH LICENCE APPLICATION FORM FOR EMBRYO BIOPSY TRAINING USING EXCESS ART EMBRYOS

Instructions for completing the Application Form are available from http://www.nhmrc.gov.au/health-ethics/human-embryos-and-cloning/information-applicants.

Under the *Research Involving Human Embryos Act 2002*, it is an offence to use excess ART embryos, create and/or use certain other embryos or undertake particular research or training involving human eggs unless the use or research or training is authorised by the NHMRC Licensing Committee, or is an exempt use.

Applicant organisation	
Application ID (NHMRC use only)	

For further information or queries relating to this Licence Application Form contact the Embryo Research Licensing:

GPO Box 1421
CANBERRA ACT 2601
Phone: 02 6217 9468
Email: embryo.research@nhmrc.gov.au

IMPORTANT NOTE

- When completing this form you should use the instructions provided in the document entitled "*Instructions for completing the simplified application form*" located at http://www.nhmrc.gov.au/health-ethics/human-embryos-and-cloning/information-applicants
- You are advised to familiarise yourself with the requirements of the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002*.
- You are also advised to consider any relevant State or Territory legislation and, if necessary, seek independent legal advice.
- Note that text boxes can be enlarged if required.
- Duplicate subsections (e.g. authorised persons & sites) as required and replace highlighted text with the required information.
- When completed the form should be saved as a pdf file and submitted by e-mail to Embryo Research Licensing at embryo.research@nhmrc.gov.au.

Section 1 — Applicant information

1.1 — Applicant Organisation

1.1.1 — Applicant organisation

Organisation name	
Street Address	
Postal address	
Courier address	
ABN or ACN	

1.1.2 — Organisation delegate

Title	
Given names	
Surname	
Position	
Telephone number	
Mobile number	
Email address	

1.1.3 — Contact person regarding this application

Title	
Given names	
Surname	
Position	
Telephone number	
Mobile number	
Email address	

1.2 — Proposed Authorised Persons

1.2.1 — Principal Supervisor

1.2.1.1 — Principal supervisor

Title	
Given names	
Surname	
Position	
Telephone number	
Mobile number	
Email address	
Role in proposed activity	[Describe the person's role in the proposed activity, including information about whether the person will be directly using excess ART embryos.]

Attach a full curriculum vitae. The CV should indicate relevant embryology or other skills.

Attachment number for CV:

1.2.1.2 — Joint or Alternate Principal supervisor (refer to Instructions for more information)

Title	
Given names	
Surname	
Position	
Telephone number	
Mobile 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 gametes.]

Attach a full curriculum vitae. The CV should indicate relevant embryology or other skills.

Attachment number for CV:

1.2.2 — Staff who will use excess ART embryos (duplicate this section as required)

Title	
Given names	
Surname	
Position	
Telephone number	
Mobile number	
Email address	
Role in proposed activity	[Describe the person's role in the proposed activity, including information about whether the person will be directly using excess ART embryos and indicating whether they will be being trained or conducting the training.]

Attach a brief curriculum vitae for each staff member. The CV should indicate relevant embryology or other skills. Additional pages can be inserted as required. If the staff member is to be trained under the licence ensure that the information specified at Item 2.8 is also provided.

Attachment number for CVs:

1.3 — Specified Sites

1.3.1 — Site (or sites) of the proposed use (duplicate this section if required)

Building name (if applicable)	
Level/room number (if applicable)	
Street number and name	
Suburb	
State and postcode	

1.3.2 — Site (or sites) of records (other than patient records) associated with the proposed use (duplicate this section if required)

Building name (if applicable)	
Level/room number (if applicable)	
Street number and name	
Suburb	
State and postcode	

1.3.3 — Site (or sites) of patient records (including original consent documents) associated with the proposed use (duplicate this section if required)

Building name (if applicable)	
Level/room number (if applicable)	
Street number and name	
Suburb	
State and postcode	

Section 2 — Project Description

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

2.1 — Title of proposed use

2.2 — Short description of the proposed use of excess ART embryos

2.3 — Proposed commencement date of licensed activity

[this should recognise the lead times associated with assessment of the licence application]

2.4 — Proposed duration of licensed activity

2.5 — Number of persons proposed to be trained

2.6 — 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	[Only required if different from the applicant organisation]
Contact name	[Only required if different from the applicant organisation]
Position	[Only required if different from the applicant organisation]
Telephone Number	[Only required if different from the applicant organisation]
Email address	[Only required if different from the applicant organisation]

2.7 — Survival rate for embryos thawed at relevant ART clinic

Provide information about the expected survival rate for thawed embryos to assist the NHMRC Licensing Committee in determining the number of excess ART embryos to be authorised for use in training. This information must be specific to the clinic(s) listed at item 2.6.

Provide an attachment if necessary and note the attachment number in this box.

2.8 – Specific Information relating to each trainee (in addition to the details required at Item 1.2.2)

1. Name of employer (if different from the applicant organisation)
2. Site of proposed training (if different from the sites listed at Item 1.3)
3. Statement of trainee's role in organisation (normally only one sentence required but further details may be needed for unusual circumstances)
4. A copy of the trainee's laboratory training record which should include:
   - Documentation that the embryologist has adequate skills in micro-manipulation of human gametes such that they can routinely perform ICSI;
   - Documentation (including dates) of previous training using animal embryos;
   - Documentation (including dates) of previous training using dead human embryos;
   - A declaration that the trainee has not previously received formal training in embryo biopsy using live human embryos and has not previously regularly performed embryo biopsies in a clinical setting.
5. A one sentence justification for training the embryologist in embryo biopsy. Possible reasons could include:
   - operational requirements due to resignation/leave or other staff movements;
   - increasing demand for Pre-implantation Genetic Diagnosis.

Section 3 — Obtaining proper consent for the use of excess ART embryos for embryo biopsy

The Licensing Committee must not issue a licence unless it is satisfied that appropriate protocols are in place to enable proper consent to be obtained before an excess ART embryo is 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, 2017* (ART Guidelines)
- *National Statement on Ethical Conduct in Human Research, 2007* - updated May 2015 (the National Statement); and
- any other relevant advice or guidelines issued by the NHMRC

Complete the *Consent Checklist for licensed activities using excess ART embryos* and attach it to the application.

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 (see Instructions for completing this form) of the declaration of excess embryos, participant information and consent forms (see item 3.2). Describe how you will ensure that you notify the Licensing Committee that proper consent has been obtained before each excess embryo is used under the licence (see RIHE Act s24(1)). Provide attachments and note the attachment numbers in this box.

3.2 — Documents to be provided to obtain proper consent

Attach a copy of all documentation intended 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.

3.3 — Payment of reasonable expenses

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.

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 — Compliance Issues

4.1 — Tracking system

Describe the tracking system that will be used to identify the excess ART embryos used in the proposed activity. Maintenance of a tracking system that links individual embryos to a specific licence and responsible persons will be a condition of a licence granted and NHMRC Inspectors will audit the system during their inspections.

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

Section 5 — Agreement to meet certain conditions

5.1 — Standard licence conditions

I declare that the applicant organisation will meet all conditions that are specified in the document *Standard Conditions of Licence* as currently published on http://www.nhmrc.gov.au/health-ethics/human-embryos-and-cloning/database-licences-authorising-use-excess-art-embryos and as amended from time to time.

5.2 — 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 excess ART embryos for embryo biopsy:

- A maximum of 15 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 (see s 9 RIHE Act) before proper consent is sought to use the excess ART embryo in the training.
- A 'suitable' embryo is an excess ART embryo which has greater than 50% of its blastomeres intact immediately following thawing or at the stage when it will be used for training.
- Unless a requirement listed below has been specifically waived by the NHMRC Licensing Committee in relation to the trainee, the Principal Supervisor must ensure that before any trainee uses an excess human ART embryo the trainee has:

  (i) not previously received training in embryo biopsy techniques using live human embryos; and

  (ii) been trained in embryo biopsy using animal embryos and dead human embryos before requesting training under this licence; and

  (iii) demonstrated skill in the micromanipulation of animal and human gametes before requesting training under this licence.
- A trainee must not use an excess ART embryo, unless the licence holder has first:

  (i) submitted an application to the NHMRC Licensing Committee for that trainee to use excess ART embryos as authorised by an issued licence, the application format for which is that specified in the document 'Application to permit Trainee to use Excess ART Embryos' currently published at https://www.nhmrc.gov.au/research/embryo-research-licensing/information-applicants, and as amended from time to time; and

  (ii) received approval in writing from the NHMRC Licensing Committee for the training of that trainee pursuant to this licence.
- When reporting, the licence holder must provide the following information to the NHMRC Licensing Committee in addition to the reporting requirements specified in the Standard Conditions:

  (i) the name and employer of each individual who has received training as authorised by an issued licence;

  (ii) the site/s where each trainee has been trained;

  (iii) how many suitable embryos have been used for or by each trainee; and

  (iv) the outcomes of the training.

5.3 — Monitoring compliance

I am aware that the conditions detailed at section 5.1 and 5.2 above will be included as conditions of any licence(s) issued and that NHMRC inspectors will audit these practices and procedures during their inspections.

5.4 — Section 5 declaration signature by organisation representative

Signature	
Date	
Printed name	
Position	Person with authority to sign on behalf of the applicant organisation

Section 6 — HREC evaluation of the proposal

6.1 — HREC contact information

6.1.1 — Name of HREC

6.1.2 — Chairperson of HREC

Title	
Given names	
Surname	
Postal address	
Courier address	
Telephone number	
Mobile number	
Email address	

Note that the Chairperson of the HREC is required to sign this application at Section 6.

6.1.3 — Secretary (or other contact person) of HREC

Title	
Given names	
Surname	
Postal address	
Courier address	
Telephone number	
Mobile number	
Email address	
Relationship to Applicant organisation	[If employee, state position within organisation.]

6.2 — HREC consideration of application

6.2.1 — Date of HREC approval

6.2.2 — HREC evaluation and approval/clearance

Attach the HREC evaluation and approval/clearance of the proposed activity and indicate the attachment number here.

Attachment number and title:

Section 7 — Signatures

I declare that to the best of my knowledge, having made reasonable inquiries, the information herein is true and correct. I understand that providing misleading information to the NHMRC, deliberately or otherwise, is an offence under Commonwealth law.

7.1 — Organisation representative

Signature	
Date	
Printed name	
Position	

7.2 — Principal Supervisor (if joint Principal Supervisors are named at 1.2.1, each one should sign the form here. Duplicate the section if required)

Signature	
Date	
Printed name	
Position	

7.3 — Chairperson of HREC

Signature	
Date	
Printed name	
Position	

Section 8 — Index of supporting information

Provide an index of supporting documentation with attachment numbers

Attachment number	Attachment title