EMBRYO RESEARCH LICENCE APPLICATION FORM

Instructions for completing the Application Form are available from http://www.nhmrc.gov.au/about/nhmrc-committees/embryo-research-licensing-committee/human-embryos-and-cloning/information-app.

Under the *Research Involving Human Embryos Act 2002*, it is an offence to use excess ART embryos, create 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 Embryo Research Licensing:

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

IMPORTANT NOTE

- When completing this form you should use the instructions provided in the document titled "*Instructions for completing application form*" which is located on the NHMRC website: http://www.nhmrc.gov.au/about/nhmrc-committees/embryo-research-licensing-committee/human-embryos-and-cloning/information-app
- 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 representative

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 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:

1.2.1.2 — 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 or human eggs, or create or use other 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 creating or using embryos or using human gametes.]

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.

Attachment number for CV:

1.3 — Specified Sites

1.3.1 — Site (or sites) of the proposed activity (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 activity (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 — ART clinic(s) or other organisation(s) from which the excess ART embryos or human eggs or other material will be obtained (duplicate this section if required)

Organisation name	
Postal 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]

1.3.4 — Site (or sites) of patient records (including original consent documents) associated with the proposed activity (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

2.1 — Proposed use of the excess ART embryos, other embryos or human eggs

Tick the activity or activities being applied for. Note that more than one may apply.

☐ (a) use of excess ART embryos (If the activity will use excess ART embryos for embryo biopsy training use the simplified application form 'Embryo Research Licence Application form for embryo biopsy training using excess ART embryos' instead)

☐ (b) creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;

☐ (c) creation of human embryos other than by fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons, and use of such embryos;

☐ (d) creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;

☐ (e) research and training involving the fertilisation of a human egg by a human sperm up to, but not including the first mitotic division, outside the body of a woman, for the purposes of research or training in ART;

☐ (f) Creation of hybrid embryos by the fertilisation of an animal egg by a human sperm and use of such embryos up to, but not including, the first mitotic division, if:

i. The creation or use is for the purposes of testing sperm quality; and

ii. The creation or use will occur in an accredited ART centre.

2.2 — Proposed commencement date of licensed activity

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

2.3 — Proposed duration of licensed activity

2.4 —Title of proposed activity

2.5 — Short description of the proposed use in lay language (this will be used to develop the description of the licensed activity published on the public database)

2.6 — Detailed description of the proposed project

Please attach a detailed description of the proposed project and note the attachment number in this box.

Provide a detailed outline of the proposed project. Include information on the following aspects of the proposed activity:

- **aims** – describe the specific aims of the project, including a clear statement of the hypothesis to be tested (if applicable);
- **background** – describe the significance of the project in relation to the existing state of knowledge and include a short review of relevant literature;
- **methodology and experimental design** – describe the research plan in detail, including as appropriate, a detailed description of the experimental design, techniques to be used and methods of statistical analysis; and
- **outcomes** – including defined endpoints of the proposed activity.

NOTE: In the event of the application being sent to external experts, any confidential commercial information would be removed from the application. Therefore, the project description should be able to be understood when this information is removed.

2.7 — Excess ART embryos, other embryos or human eggs likely to be used and justification for the number requested

Complete all applicable boxes in Section 2.7. Some projects may involve excess ART embryos and/or human eggs and/or other embryos.

In deciding whether to issue the licence, the Licensing Committee must have regard to restricting the number of excess ART embryos, other embryos or human eggs to that likely to be necessary to achieve the goals of the activity or project proposed in the application.

2.7.1 — Number of excess ART embryos likely to be necessary to achieve the goals of the proposed activity

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

2.7.2 — Number of other embryos likely to be necessary to achieve the goals of the proposed activity

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

2.7.3 — Number of human eggs likely to be necessary to achieve the goals of the proposed activity

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

2.7.4 — Justification for the number of excess ART embryos requested above.

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

2.7.5 — Justification for the number of other embryos requested above.

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

2.7.6 — Justification for the number of human eggs requested above.

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

2.8 — Likelihood of significant advance in knowledge or improvement in technologies for treatment

In deciding whether to issue the licence, the Licensing Committee must have regard to the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos or human eggs, or the creation or use of other embryos proposed in the application.

Complete all applicable boxes.

2.8.1 — Likelihood of significant advance in knowledge or improvement in technology as a result of the use of the excess ART embryos

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

2.8.2 — Likelihood of significant advance in knowledge or improvement in technology as a result of the use of human eggs

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

2.8.3 — Likelihood of significant advance in knowledge or improvement in technology as a result of the creation and/or use of other embryos

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

2.9 — Justification for why the advances described above could not reasonably be achieved by other means

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

SECTION 3 — Obtaining proper consent for the use of excess ART embryos or human eggs, or the creation or use of other embryos

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 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*, 2017
- *National Statement on Ethical Conduct in Human Research, 2007* – updated May 2015; and
- any other relevant advice or guidelines issued by the NHMRC.

Complete the relevant consent checklist available from the NHMRC website and include it with 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) of the 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 or human egg 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 copies 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 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 NHMRC Inspectors will audit the system during their inspections.

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

SECTION 5 — HREC EVALUATION OF THE PROPOSAL

5.1 — HREC contact information

5.1.1 — Name of HREC

5.1.2 — 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 8.

5.1.3 — 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.]

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 statement that is required here.

Attachment number and title:

SECTION 6 — AEC EVALUATION OF THE PROPOSAL (Only to be completed by applicants proposing to use animal eggs)

6.1 — AEC contact information

6.1.1 — Name of AEC

6.1.2 — Chairperson of AEC

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

6.1.3 — Secretary (or other contact person) of AEC

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 — AEC evaluation and approval

6.2.1 — Date of AEC approval

6.2.2 — Compliance with the NHMRC Australian code of practice for the care and use of animals for scientific purposes 8th edition 2013

Was the AEC constituted in accordance with, and acting in compliance with, the Code of Practice?

Yes ☐ No ☐

6.2.3 — AEC evaluation and approval/clearance

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

Attachment number and title:

SECTION 7 — CONFIDENTIAL COMMERCIAL INFORMTION

Does this application contain confidential commercial information?

Yes ☐ No ☐

7.1 — Identification of information

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

7.2 — Justification for treatment of information as confidential commercial information

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

SECTION 8 — 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 NHMRC, deliberately or otherwise, is an offence under Commonwealth law.

8.1 — Organisation representative

Signature	
Date	
Printed name	
Position	

8.2 — Principal supervisor

(If joint or alternate Principal Supervisors are named at 1.2.1, each one should sign the form here. Duplicate the section if required)

Signature	
Date	
Printed name	
Position	

8.3 — Chairperson of HREC

Signature	
Date	
Printed name	
Position	

SECTION 9 — INDEX OF SUPPORTING INFORMATION

Provide an index of supporting documentation with attachment numbers

Attachment number	Attachment title