Instructions: *Embryo research licence application for embryo biopsy training using excess ART embryos*

Overview

These Instructions provide detailed information about how to complete the application form for a licence to conduct training in embryo biopsy under the *Research Involving Human Embryos Act 2002* (RIHE Act). The numbering used in the instructions corresponds to the numbering on the form.

This simplified form is only for applications relating to training in embryo biopsy using excess assisted reproductive technology (ART) embryos. For all other general embryo research or training licence applications, use the standard application form. For any activity relating to mitochondrial donation techniques, use the mitochondrial donation application forms.

Embryo biopsy training using excess ART embryos can only be conducted after a licence has been issued by ERLC. Individual trainees must be approved as authorised persons under the licence before they commence their training. This approval can occur as part of the licence application or as a separate variation to the licence that occurs after the licence has been issued. If the trainee is to be authorised via a variation to the licence, provide the information specified at section 1.2.2 of the application form for each trainee.

HREC approval

Before applying for a licence, applicants must develop their proposal to use excess ART embryos for training in embryo biopsy and submit it to their human research ethics committee (HREC) for evaluation. If the HREC approves the proposal, the applicant may then apply for a licence from the National Health and Medical Research Council (NHMRC) Embryo Research Licensing Committee (ERLC).

Other considerations

Applicants should familiarise themselves with any relevant state and/or territory legislation and, where necessary, seek independent legal advice.

When completing the application form, note the following general instructions:

- Duplicate relevant sections of the form as required (for example, proposed authorised persons, sites where excess ART embryos or eggs may be obtained etc)
- Responses to all questions should be as comprehensive as possible - failure to provide adequate information may result in delays in consideration of the application
- Incomplete applications will be returned for revision before assessment commences
- Ensure that current CVs are provided (where indicated)
- Submit the complete application, including attachments, via email to embryo.research@nhmrc.gov.au
- Embryo Research Licensing will provide written acknowledgment of the receipt of the application within 2 working days. The acknowledgment will include an application number, which must be used in subsequent correspondence.

Applicants may be asked to provide additional written information to assist ERLC to reach a decision.

Reference documents

Documents that may be useful in completing this application are listed below.

Legislation available from the Federal Register of Legislation website (www.legislation.gov.au/):

- *Research Involving Human Embryos Act 2002*
- *Prohibition of Human Cloning for Reproduction Act 2002*
- Research Involving Human Embryos Regulations 2017.

Guidelines available from the NHMRC website (www.nhmrc.gov.au):

- *National Statement on Ethical Conduct in Human Research* (the National Statement)
- *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (the ART Guidelines)
- Objective criteria on embryos that are unsuitable for implantation.
- The *Australian Code for the Responsible Conduct of Research* (the Code).

The National Statement and the ART Guidelines are prescribed by the Research Involving Human Embryos Regulations 2017 in relation to licence applications.

NHMRC's Privacy Policy is available on our website at: www.nhmrc.gov.au/privacy.

Application sections

The following information provides guidance for completing each section of the application form. The section numbering corresponds to the form.

Section 1 — Applicant information

Section 1 requires information on the entities, people and sites involved in the proposed licence activity. Table 1 outlines the responsibilities of the entities and people involved in the activity.

Section 1.2.2 must be completed for each trainee and trainer (for trainers that are not listed as a Principal Supervisor). For variations to include a trainee/trainer after a licence has been issued, licence holders are required to submit the information in this section for each proposed new trainee/trainer as part of the applicant to vary the licence (RIHE Act s25).

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. The Principal Supervisor is responsible for confirming that each proposed authorised person is competent to be included on the licence.

Specified sites are the locations where the authorised uses will be conducted, relevant records are stored, and excess ART embryos may be sourced. Licensed activities must only occur at the sites listed at section 1.3.1. Sites of Records (sections 1.3.2 and 1.3.3) are the locations at which records relating to the activity will be stored.

Section 2 — Project description

This application form is specific to the use of excess ART embryos in embryo biopsy training. The proposed title and activities for the licence in sections 2.1 and 2.2 are standardised for this licence type.

Applicants should select the standard title and description for the licence where they accurately reflect the proposed activity, or provide an alternative title and/or description (with an explanation) if the standard options provided do not describe the planned activity.

Major amendment of the standard options may indicate that a different type of general licence under the RIHE Act should be applied for.

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 is used (RIHE Act s21(3)(a)).

3.1 Overview of proper consent process

The *Consent checklist for licensed activities using excess ART embryos* (available from the NHMRC website) has been prepared to assist applicants to develop consent processes that satisfy the legislative requirements.

Section 3.1 requests a flowchart. The flowchart description and flowchart (timeline) must clearly indicate:

- when information will be supplied to responsible persons
- when proper consent will be obtained from each responsible person, and

  when you will notify ERLC that proper consent has been obtained before each excess ART embryo is used under the licence and any restrictions that may have been placed on that consent (RIHE Act s24(1)(b)).

3.2 Tracking system

Licence holders are required to maintain a tracking system that uniquely identifies each excess ART embryo used. Any issued licence will be required to maintain a tracking system that links individual embryos to a specific licence, signed consent documents, responsible persons and outcomes of the use of the material. Embryo Licence Inspectors will audit the system during inspections.

An outcome must be recorded for each embryo used under the licence – refer to the 'authorised use' spreadsheet for the Licence Holder six-monthly and final reports to ERLC located on the Information for Licence Holders page of the NHMRC website.

3.3 Documents to be provided to obtain proper consent

A copy of the proposed declaration of excess ART embryos form, proper consent form (e.g. Patient Information and Consent Form for this specific training activity) and all written information relating to the licensed use of embryos that will be provided to potential embryo donors must be attached to the application form.

Ensure that the documents use language that will be readily understood by potential participants/donors and that the documents have been reviewed for completeness, clarity and accuracy. Refer to the consent checklist for details of the information required in the consent documents.

Section 4 — Agreement to meet certain conditions

Licence holder compliance with conditions is monitored by Embryo Licence Inspectors.

4.1 Standard Conditions

The Standard Conditions of General Licences are on the NHMRC website. These conditions apply to all general licences issued by ERLC, including embryo biopsy training licences.

Section 4.1 advises that by signing the application form the applicant confirms that they are able to meet the Standard Conditions of the licence.

4.2 Special Conditions

Section 4.2 of the form lists special conditions which apply specifically to this general licence type (i.e. a licence that authorise use of excess ART embryos for training in embryo biopsy).

4.3 Monitoring compliance

By signing the application (section 6), the applicant organisation and Principal Supervisor acknowledge that compliance with the conditions listed in section 4 will be monitored by Embryo Licence Inspectors.

Section 5 — HREC Approval

The RIHE Act requires ERLC to have regard to the HREC's assessment of the proposed activity (i.e. embryo biopsy training) as part of its assessment.

The approving HREC must be registered by NHMRC and constituted in accordance with, and acting in compliance with, the National Statement. For more information see www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees.

At section 5.2, evidence of the HREC evaluation is required. The statement should be authorised by the HREC (e.g. signed by the Chair or HREC Secretariat) and include confirmation that:

- the full details of the HREC decision were recorded
- at least eight members fulfilling the minimum membership roles participated in the decision, whether by attendance at a meeting or otherwise
- no member who participated in the decision had a relevant conflict of interest, and
- the research proposal and consent procedures and documents were considered in the light of the National Statement and ART Guidelines.

The statement must include a summary of the reasoning that supported the HREC decision, and a summary of the reasons for being satisfied that the proposal conforms to the National Statement and the ART Guidelines.

HRECs should also take any procedural advice published by ERLC into consideration.

Section 6 — Signatures

This section requires signatures from the relevant people as listed in section 1. By signing that application form the Organisation and Principal Supervisor are confirming the accuracy of information provided and the ability of the licence holder (if a licence is issued) to comply with licence conditions.

Section 7 — Index of supporting information

Provide an index of all supporting information attached to the application form.

Table 1. Roles and Responsibilities

Role	Responsibilities
1.1.1. 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.
1.1.2. 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	The Embryo Research Licensing team will contact this person with any queries regarding the application. The contact person may be the organisation representative (see 1.1.2), the Principal Supervisor (see 1.2.1) or another person within the applicant organisation. The contact person must be familiar with the application.
1.2 Proposed Authorised Persons	Any person who will use excess ART embryos in the licensed activity must be authorised by the licence to do so. This includes staff members who will conduct the training activities and the people who will be trained. Variations to the licence may be used to add or remove authorised persons during the lifetime of the licence.
1.2.1.1. Principal Supervisor	The authorised person who will oversee the proposed activity and will ensure compliance with the legislation and licence conditions if a licence is issued. The Principal Supervisor is the person who will be responsible for supervising the use of excess ART embryos in the activity authorised by the licence. 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. The Principal Supervisor (or an alternate Principal Supervisor, if any) must oversee all blastocyst biopsies conducted under this licence. The Standard Conditions of Licence require the licensed activity to stop if the Principal Supervisor leaves the organisation or is temporarily unable to perform the duties of the Principal Supervisor (refer to Standard Conditions of Licence). For this reason the applicant organisation may choose to nominate joint Principal Supervisors or a Principal Supervisor and an alternate supervisor to maintain continuity of oversight.
1.2.1.2. Joint Principal Supervisor	Shares the same responsibilities with the Principal Supervisor at all times.
1.2.1.2. Alternate Principal Supervisor	Will take on the role and responsibilities of the Principal Supervisor only when the Principal Supervisor (and Joint Supervisor if applicable) is absent. The licence holder must document the absence of the Principal Supervisor specifying each period where the Alternative Principal Supervisor is responsible for the licensed activity.

1.2.2. Staff who will use excess ART embryos	Persons authorised to use excess ART embryos or other embryos should have experience in handling embryos. 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.

APPLICATION CHECKLIST

Use the checklist below to ensure that you have completed all steps in the licence application process.

Have you:	Yes/No
Developed a detailed proposal and submitted it to your HREC for approval?	
Received HREC approval?	
Attached the written evaluation prepared by the HREC?	
Completed all sections of the application form?	
Ensured that the consent documents and process accurately reflect the project described in the application form?	
Considered the applicable consent checklist when developing the consent process and documents?	
Obtained all signatures required in section 6 of the application form?	
Proof-read the application and attachments?	