INSTRUCTIONS FOR COMPLETING THE EMBRYO RESEARCH LICENCE APPLICATION FORM

These notes provide detailed information about how to complete the Embryo Research Licence (ERL) Application Form for a licence under the *Research Involving Human Embryos Act 2002*. The numbering used in the instructions corresponds to the numbering on the form. If applying for a training licence, refer to the Application form for training in embryo biopsy and related instructions.

HUMAN RESEARCH ETHICS COMMITTEE APPROVAL

Before applying for a licence, applicants must develop their proposal to use excess assisted reproductive technology (ART) embryos, use human eggs and/or create or use other embryos 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 (the NHMRC Licensing Committee).

The application submitted to the Licensing Committee must be obviously similar to or a subset of the application approved by the HREC.

OTHER CONSIDERATIONS

Applicants will need to familiarise themselves with any relevant State and Territory legislation and, where necessary, seek independent legal advice.

When completing the ERL Application form, note the following general points:

- Duplicate relevant sections of the form as required (e.g. proposed authorised persons, sites where excess ART embryos or eggs may be obtained etc.)
- Responses to all questions must be as comprehensive as possible - failure to provide adequate information **will** result in delays in consideration of the application.
- Proof-read the application and its attachments, particularly the consent documents.
- Incomplete applications will be returned for revision before assessment commences.
- Ensure that current CVs are provided.
- Submit the application via e-mail to embryo.research@nhmrc.gov.au. The signature page may be submitted as a scanned version. If the application is submitted as a hard copy send it to:

  NHMRC Embryo Research Licensing
  GPO Box 1421
  CANBERRA ACT 2601
- Embryo Research Licensing will provide written acknowledgment of the receipt of the application within 5 working days. The acknowledgment will include an application number, which must be used in subsequent correspondence.

Applicants may be required to provide additional written information to assist the NHMRC Licensing Committee to reach a decision.

A working group of the NHMRC Licensing Committee may ask for a teleconference with or to meet the applicant to clarify the information provided.

Documents that may be useful in completing the ERL Application Form are listed below.

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

- *Research Involving Human Embryos Act 2002* (the RIHE Act);
- *Prohibition of Human Cloning for Reproduction Act 2002* (the PHCR Act); and
- Research Involving Human Embryos Regulations 2017.

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

- *National Statement on Ethical Conduct in Human Research 2007* – updated May 2015 (the National Statement);
- *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*, 2017 (the ART Guidelines);
- *Objective criteria on embryos that are unsuitable for implantation;*
- *Australian code of practice for the care and use of laboratory animals for scientific purposes 8th edition 2013;* and
- *The Australian Code for the Responsible Conduct of Research 2007* (the Code).

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

COMPLETING THE APPLICATION FORM

The following sections provide detailed instructions for completing each component of the ERL Application Form. The numbering corresponds to the form.

Section 1 — Applicant Information

Applications from joint applicants may be submitted, but the following must be taken into consideration before deciding to lodge a joint application:

- The issue of a licence will impose legal duties and obligations on licence holders, including obligations to track and report usage of human embryos and eggs;
- Severe penalties, including imprisonment, may apply in the event of failure to comply with licence conditions;
- The issue of joint licences may complicate tracking and reporting requirements for licence holders;
- The actions of one joint applicant may expose other joint applicants to legal liability.

Applicants are advised to seek legal advice on the implications of sharing responsibility for complying with licence conditions and legislative requirements. Examples of licence conditions that may apply are available on the NHMRC Licensing Committee's public database of licences.

When more than one organisation is applying for the licence, this section of the form must be completed to include details for each organisation. However, only one contact person should be listed.

1.1 — Applicant Organisation

1.1.1 — Applicant organisation

The applicant organisation will generally be a legal corporate entity/organisation and not an individual researcher or ART clinician. This organisation will be the licence holder and will be responsible for ensuring compliance with licence conditions. The issue of a licence will impose legal obligations and responsibilities on the organisation named here.

- Provide the requested details relating to the university, ART clinic, hospital or research centre in which the proposed research will be conducted.

1.1.2 — Organisation representative

This person must have authority to sign the application on behalf of the organisation; for example, the head of a department in a university or the director of an ART clinic.

- Provide the required details for the person who is representing the organisation applying for the licence.

1.1.3 — Contact person

Embryo Research Licensing 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.

- Provide the required details for the person within the organisation who will act as the contact point in relation to the application.

1.2 — Proposed Authorised Persons

Only those people listed on the licence as 'Authorised Persons' are permitted to use excess ART embryos or human eggs, or create or use other embryos.

- The people nominated here should have demonstrable skills and experience to perform the licensed activity.
- Do not list all people associated with the project, only those who will perform an activity for which a licence is required. People who only undertake downstream activities such as culturing stem cells do not need to be authorised by a licence to do so.

1.2.1 — Principal Supervisor
The person nominated as the Principal Supervisor must have technical insight into all aspects of the proposed activity and sufficient authority to fulfil the role described below. This person could, for example, be the principal investigator or researcher or, in the case of an ART clinic, the chief scientist or director of clinical sciences.

The Principal Supervisor is the authorised person who will:

- oversee the proposed activity
- ensure compliance with the legislation and licence conditions if a licence is issued, and
- be responsible for supervising the use of excess ART embryos or human eggs, or the creation of use of other embryos in the activity authorised by the 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. The Licensing Committee will deem joint principal supervisors to have shared responsibility for the licensed activity at all times. An alternate principal supervisor only takes responsibility for the licensed activity in the absence of the principal supervisor.

- Provide contact details for the principal supervisor and attach a full curriculum vitae. This information will enable the NHMRC Licensing Committee to determine whether the nominated Principal Supervisor has appropriate knowledge and skills to take responsibility for supervision of the use of the excess ART embryos or human eggs, or the creation or use of other embryos.

1.2.2 — Staff who will use excess ART embryos or human eggs, or create or use other embryos
Persons authorised to use excess ART embryos or other embryos should have experience in handling human embryos. Persons authorised to use human eggs to create other embryos should have experience in handling human and/or animal gametes.

To assist applicants in determining the persons who will need to be authorised under a licence, the following advice is provided:

- Any person who uses human eggs in a process to create an embryo under paragraphs 20(1)(b), (c) or (d) of the RIHE Act will need to be authorised by a licence to do so.
- Any person fertilising a human egg by a human sperm outside the body of a woman, for the purposes specified by paragraph 20(1)(e) of the RIHE Act, will need to be authorised by a licence to do so.
- The **creation** of “other embryos” must be performed by authorised persons.
- With regard to the **use** of “other embryos”, any activity after the creation of the embryos is considered to be a “use” up to, and including, the point of destruction of the created embryo and must be performed by authorised persons.
- With regard to excess ART embryos, some uses are exempt under s. 10(2) of the RIHE Act. All other uses must be performed by authorised persons up to, and including, the point that the embryo is destroyed or is allowed to succumb. For example, the staff member who will isolate the inner cell masses from embryos during a project to develop new embryonic stem cell lines must be authorised by the licence to do so.

This section of the form should be duplicated and completed for each person who is to be authorised to use excess ART embryos or human eggs, or create or use other embryos in the 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 outlining relevant qualifications and experience.

1.3 – Specified Sites

Specified sites are the locations where:

- the authorised activity will be conducted
- relevant records are stored
- the human embryos and/or eggs intended for use in the authorised activity may be stored, obtained or created.

1.3.1 — Site(s) of the proposed activity

Licence holders must restrict licensed activities to the nominated sites.
For each site:

- include detailed information about the location at which the proposed research will occur.
- be as specific as possible and include laboratory room number and building name where available.

1.3.2 — Site(s) of records (other than patient records) associated with the proposed activity

- Provide information about the location of records (other than patient records) associated with the proposed activity.
    - This includes laboratory notebooks and research records related to the authorised activity (e.g. records covering embryo thaw, authorised activity, and outcome of use) and electronic records (e.g. database of activity and outcomes).

1.3.3 — ART clinic or other organisation from which the excess ART embryos or human eggs or other material will be obtained

- Provide information about the source of excess ART embryos or human eggs.
    - This may be the applicant organisation using excess ART embryos or human eggs obtained in its clinic or from one of its regional facilities.
- Where the proposed activity may be conducted by an organisation that is not an ART clinic, provide information about the ART clinic(s) from which the excess ART embryos or human eggs are proposed to be obtained.
- Provide details about the source(s) of any other human gametes, cells, tissues or genetic material to be used in the project.

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

- Provide information about the location of patient records (including signed consent documents) associated with the proposed activity. For example, if excess ART embryos will be sourced from several ART clinics and these clinics will retain the original patient records, list the clinics here.
- If patient records relating to licensed activities may be stored at a separate site (such as archival storage), also list that site here.

Section 2 – Project Description

The RIHE Act allows a person to apply for a licence for one or more of the activities listed in s. 20(1). The application must be made in accordance with the requirements of the NHMRC Licensing Committee under s. 20(2) of the RIHE Act. Applicants are requested to limit the scope of individual applications so that an application describes a single defined project or licensable activity. This will assist the NHMRC Licensing Committee to consider the application more efficiently and will reduce the assessment time. It will also simplify the development of consent documents for the project and will assist the applicant organisation to comply with licence conditions if the application is approved.

Any applicant unsure of whether to apply for one or more licences should contact Embryo Research Licensing for advice.

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

Several types of activity are licensable under subsection 20(1) of the RIHE Act. Some projects may involve more than one category of activity. Indicate every category that will apply.

2.2 — Proposed commencement date

Indicate the date on which the applicant proposes to begin use of excess ART embryos or human eggs, or creation or use of other embryos. Activity cannot commence until authorised by a licence. As consent must be obtained in accordance with protocols approved by the NHMRC Licensing Committee, prospective donors cannot be approached until after the licence has been issued.

2.3 — Proposed duration of activity

A licence is required for the use of excess ART embryos or human eggs, or the creation or use of other embryos in research and not for research *per se*. For example, if a research project involves five stages over three years but only the third stage of the project involves the use of excess ART embryos, then a licence would only be needed for the duration of the third stage and not for the entire three years.

- Provide a realistic timeframe for the duration of the proposed activity involving the use of excess ART embryos or human eggs, or creation or use of other embryos.
- If the proposed activity will be ongoing, such as quality assurance or training activities in an ART clinic over the course of a year or more, insert the word ‘ongoing’ in this part of the ERL Application Form. The NHMRC Licensing Committee will then determine an appropriate expiry date for the licence.

2.4 — Title of proposed activity

If an organisation or individual is applying for a number of licences for different activities the titles of the projects should clearly distinguish each separate activity. The title used here will be made available on the NHMRC Licensing Committee’s public database.

- Provide a short title (one or two lines) to enable identification of the activity for which a licence is sought.

2.5 — Short lay statement about the nature of the proposed activity

If a licence is granted, this short statement will be used by the NHMRC Licensing Committee to develop the description of the authorised use that is included on the public database of licences. The statement should therefore be easily understood by a member of the public and must not include details that are deemed to be commercially confidential (see Section 7 below).

- Provide a short statement (one or two paragraphs) describing in lay terms the proposed use of the excess ART embryos or human eggs, or creation or use of other embryos.

2.6 — Detailed description of the proposed project
Sufficient detail must be provided to allow the NHMRC Licensing Committee (and its external experts, if necessary) to gain a clear understanding of the aims of the proposal and the precise nature of the activity involving the use of excess ART embryos or human eggs, or creation or use of other embryos, including whether embryos or eggs will be damaged or destroyed.

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

- **Aims/goals** – 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. Describe how the project will fit into the organisation's or research group's broader research framework, paying particular attention to describing the limits or boundaries of the current project in relation to the overall research framework. For example, a research group's overall goal may be to use embryonic stem cells derived from cloned embryos to study a particular disease. However the aim of the current application may be to demonstrate that it is possible to derive an embryonic stem cell line from an embryo created by SCNT. Provide any preliminary data from animals or stem cell lines that support the proposed project;
- **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** – outline defined endpoints of the proposed activity, taking the proposed duration of the project into account. These endpoints should include both positive and negative outcomes. In the SCNT example above, the positive end point of the licensed activity might be the repeatable demonstration of successful SCNT by derivation of 10 embryonic stem cell lines. A suitable negative endpoint might be that the project would cease if no SCNT embryos had been obtained after a specified number of eggs had been used. The NHMRC Licensing Committee considers that most projects would have definite endpoints which will allow the NHMRC Licensing Committee and the researchers to know that a project has been completed.

External experts may be consulted to assist the NHMRC Licensing Committee in assessing the scientific merit of an application and the likelihood of a significant advance in knowledge. In this situation, any confidential commercial information will be removed from the application. Therefore, the project description should be able to be understood when this information is removed. No-one with a conflict of interest will be asked to provide advice. Applicants will have the opportunity to respond to any adverse comment although the identity of the commentator will not be displayed.

An application for a licence under paragraphs 20(1)(e) or (f) of the RIHE Act must include information on how the applicant will ensure that the activity ceases before the first mitotic division occurs. In relation to licences under paragraph 20(1)(e), the NHMRC Licensing Committee has determined that the activity must be terminated within 20 hours from the time of insemination. In relation to licences under paragraph 20(1)(f), the NHMRC Licensing Committee has determined that the activity must be terminated immediately after the appearance of pro-nuclei. In order to facilitate monitoring of these activities, licences will require the times of insemination, pro-nuclei check and discard to be reported. That is, researchers will be required to document their observations and provide them when requested by NHMRC inspectors.

2.7 — Excess ART embryos, other embryos or human eggs likely to be used and justification for the number requested
In deciding whether to issue the licence, paragraph 21(4)(a) of the RIHE Act specifies that the NHMRC 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. When issuing a licence the NHMRC Licensing Committee is required by paragraph 24(5)(b) of the RIHE Act to set conditions which specify the number of excess ART embryos, other embryos or human eggs authorised to be created or used under the licence.

When this requirement is considered in conjunction with the requirement for the NHMRC Licensing Committee to have regard to the likelihood of significant advance in knowledge or improvement in technologies for treatment (paragraph 21(4)(b)), the NHMRC Licensing Committee considers that any licence should be issued for the maximum number of embryos or eggs required to successfully achieve the goals of the licence.

Furthermore, it is the NHMRC Licensing Committee's view that the best experiment is not necessarily the one which uses the fewest embryos or eggs in an absolute sense. Rather, it is the experiment which is designed to give the most reliable answer to the question being asked and, in most cases, which permits a statistically significant outcome. Poor experimental design can lead to the use of more eggs or embryos than necessary because the results may be ambiguous or unreliable and the experiments must therefore be repeated.

2.7.1 – 2.7.3 — Number of excess ART embryos, other embryos or human eggs likely to be necessary to achieve the goals of the proposed activity

- State the maximum number of excess ART embryos, other embryos or human eggs likely to be necessary to achieve the goals of the proposed activity.

2.7.4 – 2.7.6 — Justification for the number of excess ART embryos, other embryos or human eggs requested above

- Provide detailed information that explains **why** the number of excess ART embryos, other embryos or human eggs is considered to be necessary to achieve the goals of the proposed activity or project (refer to paragraph 21(4)(a) of the RIHE Act).
- Provide information on statistical calculations where relevant, including power calculations and the software used to determine them. Include information about the survival rate of embryos removed from storage and the percentage expected to grow to the required developmental stage, if relevant.
- With respect to human eggs, comment on the stage of maturity and/or clinical suitability necessary for the activity, the proportion of eggs likely to be at the appropriate stage, and what will happen to any eggs not suitable to be used, and the implications for the donors' chances of achieving a successful pregnancy. Information must be specific to the clinic from which the excess ART embryos or human eggs are obtained.
- It is also important that the required numbers of embryos or eggs are likely to become available within the proposed time frame of the licensed activity. Provide information about categories of patients who will be approached, the number of cycles conducted each year within these categories, expected numbers of suitable eggs or embryos per cycle and the estimated rate of consent.

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

In deciding whether to issue the licence, paragraph 21(4)(b) of the RIHE Act specifies that the NHMRC 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.

2.8.1 – 2.8.3 — Likelihood of a significant advance in knowledge or improvement in technology as a result of the use of the excess ART embryos or human eggs or creation or use of other embryos

Licence applicants must provide specific information about how the proposed use of excess ART embryos or human eggs or creation or use of other embryos will result in a significant advance in knowledge or improvement in technologies for treatment.

- Include information on the track record and qualifications of researchers involved in the project that support the likelihood of success of the research proposal.
- If the project involves derivation of embryonic stem cell lines, explain how the new cell lines will allow an advance in knowledge or improvement in technology that is not possible with existing cell lines.

The NHMRC Licensing Committee follows the *Guidelines for the Conduct of Human Embryonic Stem Cell Research* issued by the International Society for Stem Cell Research in 2007 (available from the ISSCR website http://www.isscr.org). Section 12 of these guidelines states that:

"Proposals for derivations of new human pluripotent stem cell lines should be scientifically justified and executed by scientists with appropriate expertise. Hand-in-hand with the privilege to perform derivations is the obligation to distribute the cell lines to the research community. A clear, detailed outline for banking and open access to the new lines should be incorporated into derivation proposals. New pluripotent stem cell lines should be made generally available as soon as possible following derivation and first publication. The ISSCR encourages researchers to deposit lines early into centralized repositories where the cell lines will be held for release and distribution upon publication."

- Indicate how any new human embryonic stem cell lines derived in the project will be made available to the research community or provide reasons why this will not occur.
- Attach to the ERL Application Form any relevant information supporting the claims made and note the attachment number(s) in the box provided at this item number.

Where applicable, the NHMRC Licensing Committee will review the results of previous research under other licences held by your organisation when considering the current application.

- Attach copies of any relevant publications from your organisation not previously provided to the committee.

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

The justification could include information about the state and limitations of research in other model systems and why such systems will not provide the required data and why it is necessary to progress to the use of human embryos or eggs.

- Provide information on why the use of excess ART embryos or human eggs, or the creation or use of other embryos is essential to the project and why the aims of the project could not be otherwise achieved (see paragraph 21(4)(b) of the RIHE Act).

Section 3 — Obtaining Proper Consent for the use of excess ART embryos or human eggs, or creation or use of other embryos

The NHMRC 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 (see paragraph 21(3)(a) of the RIHE Act). The 'Consent checklist for licensed activities using excess ART embryos' and 'Consent checklist for other licensed research' have been prepared to assist applicants to develop consent processes that satisfy the legislative requirements.

Complete the applicable checklist (available from the NHMRC website) as you develop the protocol and documents and attach it to your application.

3.1 — Overview of proper consent process

Applicants must provide detailed information about the proposed protocols for obtaining proper consent from all responsible persons. As required by section 8 of the RIHE Act and the Research Involving Human Embryos Regulations 2017, proper consent is consent obtained in accordance with the 2017 ART Guidelines.

A definition of responsible person is given in section 8 of the RIHE Act and this should be kept in mind to ensure that proper consent will be obtained from **all** responsible persons. Particular care is required if you propose to request consent for research from people who have had or are having treatment cycles using donor gametes. Depending on the circumstances up to six people may be required to give consent to the research (see Box 2.1 in Chapter 2 of the Information Kit which can be accessed from the Information for Applicants page of the NHMRC website).

The description and flowchart (timeline) must clearly indicate the following:

- when information will be supplied to responsible persons;
- when proper consent will be obtained from each responsible person;
- how the process relates to constraints imposed by the timing of clinical treatment and the experimental procedures involved; and
- when you will notify the NHMRC Licensing Committee that consent has been obtained to create and/or use the excess ART embryo, human egg or other embryo and any restrictions that may have been placed on that consent as required by subsection 24(1) of the RIHE Act.

The proper consent process required will vary depending on whether the licensed activity involves the use of excess ART embryos, other embryos or human eggs and must be in accordance with the 2017 ART Guidelines. When developing the consent process, the National Statement and any advice issued by the Licensing Committee should also be consulted.

Describe your strategy for determining who you will approach to request their donation of excess ART embryos, gametes, cells or genetic material to your project. For example, if the project involves the use of human eggs, indicate whether the eggs will be donated by women undergoing ART treatment cycles or whether they will be donated by women purely for the research project.

With respect to egg donors undergoing ART and willing to donate a proportion of eggs from their treatment to research, the consent documents must clearly describe how eggs will be allocated between donor and research. Note that this does not refer to the overall numbers allocated to each but to the decision-making process which determines how each egg, on an individual basis, is allocated between donor and research. The egg donor must be consulted about this, and her decision will determine the process adopted.

If you propose to request donation of clinically useful eggs to research explain why this is necessary, particularly if you propose to approach women during their first ART treatment cycle. Include information on the ethical, clinical and scientific implications of the women's decisions and explain how you will ensure that consent to participate in the research is fully informed, competent, voluntary and specific.

If you propose to use fresh embryos which are unsuitable for implantation according to the objective criteria or because they have been identified by preimplantation genetic diagnosis as carrying a serious genetic disorder, or eggs which are unsuitable for clinical use, the consent process must include time for reconsideration after the eggs or embryos have been determined to be unsuitable for clinical use but before they enter the licensed activity. Where eggs are being donated to licensed research this period must be long enough to allow the woman to have recovered from the anaesthetic or sedation used during egg retrieval.

- Provide information about how this period for withdrawal of consent will be managed e.g. by provision of a voicemail service which is routinely checked before eggs or embryos are used in the licensed activity.

Outline any arrangements with ART clinics and outside researchers to ensure that the authorised persons use only embryos, human eggs, reproductive material, genetic material or cells for which proper consent has been obtained.

Provide information about how the organisation will record and handle any restrictions that responsible persons may place on their consent to use of their gametes, embryos, cells or genetic material in the research project.

3.2 — Documents relating to obtaining proper consent
A copy of the proposed declaration of excess ART embryos form (if required), proper consent form and all written information intended to be provided to **all** potential donors must be attached to the ERL 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 checklists for details of the information required in the consent documents.

Important note: Do not attach any signed consent forms or forms containing personal information about donors.

3.3 — Payment of reasonable expenses
Section 21 of the PHCR Act allows for reimbursement of reasonable expenses incurred by a person in connection with the supply of a human egg, human sperm or human embryo. The giving or receiving of 'valuable consideration' is prohibited.

The PHCR Act imposes severe penalties for giving, receiving, offering to give or offering to receive valuable consideration for the supply of a human egg, human sperm or human embryo. Valuable consideration includes any inducement, discount or priority in the provision of a service. Applicants are advised to obtain legal advice on this issue and to consult the National Statement and ART Guidelines.

- Indicate how you will determine the amounts (if any) and categories of expenses to be reimbursed to gamete donors or suppliers.

Section 4 — Compliance Issues

Under the RIHE and PHCR Acts, NHMRC has responsibility for monitoring compliance with the legislation, including compliance with licence conditions. To achieve this, the chairperson of the NHMRC Licensing Committee has appointed inspectors to monitor compliance and report their findings to the committee. In order to facilitate monitoring of licensed activities, licence holders are required by Standard Condition 4101 to maintain a tracking system that uniquely identifies each excess ART embryo or human egg used or other embryos created or used.

4.1 — Tracking system

Maintenance of a tracking system that links individual embryos and/or eggs to a specific licence, signed consent documents, responsible persons and outcomes of the use will be a condition of any issued licence. NHMRC Inspectors will audit the system during their inspections. An outcome must be recorded for each embryo and/or egg used – refer to the 'authorised use' spreadsheet for the Licence Holder six-monthly and final reports to the Licensing Committee located on the Information for Licence Holders page of the NHMRC website.

- 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.

Section 5 — HREC evaluation of the proposal

The chair of the Human Research Ethics Committee (HREC) will be required to validate Section 5 of the form before signing the application at Section 8.

Before a licence can be issued, the proposed activity must be assessed and approved by a HREC registered by NHMRC and which meets the requirements of Section 5.1.30 of the National Statement. As part of its assessment process, the NHMRC Licensing Committee must be satisfied that the relevant HREC is constituted in accordance with, and acting in compliance with, the National Statement and have regard to the HREC's assessment of the application.

5.1 — HREC contact information

5.1.1 — Name of HREC

- Provide the full name of the HREC that has evaluated the proposal. If the applicant organisation has more than one HREC, the name of the HREC must make it clear which HREC evaluated the proposal.

  In some cases, the proposal may involve approval from a number of different HRECs. If this applies, details must be provided for each HREC, and the chairperson of each HREC must sign the ERL Application Form. Duplicate the appropriate sections of the form as required.

5.1.2 — Chairperson of HREC

- Provide the full name and contact details of the chairperson of the HREC.

5.1.3 — Secretary (or other contact person) of HREC

The NHMRC Licensing Committee is required to notify the HREC of its decision regarding the licence application. The person whose name and contact details are included in this field will be the person notified by the committee.

- Indicate the relationship (if any) of this person to the Applicant organisation.

5.2 — HREC consideration of application

5.2.1 — Date of HREC approval

- Provide the date on which the HREC gave final approval to the proposal.

5.2.2 — HREC evaluation and approval/clearance

A statement signed by the chair of the HREC must be appended. The statement should include confirmation that:

- the full details of the HREC decision were recorded
- at least eight members fulfilling the minimum membership categories participated in the decision, whether by attendance at a meeting or otherwise
- no member who participated in the decision had a conflict of interest
- 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 the NHMRC Licensing Committee into consideration.

As noted in the introduction to this section, the NHMRC Licensing Committee will pay particular attention to whether the HREC was constituted in accordance with, and acting in compliance with, the National Statement. Matters that the chairperson of the HREC should consider when verifying that the HREC was constituted in accordance with, and acting in compliance with, the National Statement include, but are not limited to, the following:

- The minimum membership of the HREC (listed in paragraph 5.1.30 of the National Statement) must have received all relevant papers and attended a meeting or meetings at which the HREC decision was reached.

- Where not all of the minimum membership attended that meeting or meetings, whether the minimum membership had an opportunity to contribute their views and have the views recorded before a decision in relation to the proposal was reached.
- No single member should fulfil more than one role – that is, the minimum membership should comprise eight different individuals.
- Consideration of the proposal was not undertaken by any member who had a conflict of interest, including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research.
- The full details of the HREC decision were recorded.

Section 6 — AEC evaluation of the proposal

This section of the form only needs to be completed for projects that involve the use of animal eggs for sperm quality testing, category (f) in section 2.1.

6.1 — AEC contact information

6.1.1 — Name of AEC

- Provide the full name of the Animal Ethics Committee (AEC) that has evaluated the proposal. If the applicant organisation has more than one AEC, the name of the AEC must make it clear which AEC evaluated the proposal.

6.1.2 — Chairperson of AEC

- Provide the full name and contact details of the chairperson of the AEC.

6.1.3 — Secretary (or other contact person) of AEC

- Provide the contact details of the person that the NHMRC Licensing Committee should contact if they have any queries for the AEC.

6.2 — AEC evaluation and approval

6.2.1 — Date of AEC approval

- Provide the date on which the AEC gave final approval to the proposal. Indicate the date on which the validity of the approval ceases.

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

The AEC that approved the proposed activity contained in this application must be constituted in accordance with the *Australian code of practice for the care and use of laboratory animals for scientific purposes 8th edition 2013*. This includes details about the appropriate membership (composition) of AECs and appropriate procedures to be adopted by AECs (including in relation to meetings, conflict of interest and recording of decisions).

6.2.3 — AEC evaluation and approval/clearance

- Attach a statement signed by the Chair confirming that the committee has approved the use of animals in the proposed project.

Section 7 — Confidential Commercial information

Members of the NHMRC Licensing Committee are bound by the confidentiality provisions of section 30 of the RIHE Act. This creates an offence for the disclosure of confidential commercial information that the member has only because he or she is performing functions under the Act.

Members are also bound by the NHMRC's Disclosure of Interest Policy, which requires declaration of any interests which may be relevant to matters being considered by the committee.

NHMRC staff are similarly bound by the RIHE Act and by the Australian Public Service Code of Conduct[1] and applicable Criminal Code provisions.

7.1 — Identification of information

- Identify the precise location of any confidential commercial information within the application by cross-referencing the section number, as well as page, paragraph and sentence identification where necessary. For example:
  The information is in Section 2.6, page 6, paragraphs 2 to 6 inclusive, and the first two sentences of paragraph 7.

In the event of the application being sent to external experts (see also Section 2), any confidential commercial information would be removed from the application. Therefore, the project description must be able to be understood when this information is removed.

7.2 — Justification for treatment of information as confidential commercial information

In order for information to be treated as confidential commercial information, it must have commercial or other value that would or could reasonably be expected to be destroyed or diminished if the information were disclosed.

- Outline the reasons for requesting that the information identified in Section 7.1 be treated as confidential commercial information.

[1] http://www.apsc.gov.au/working-in-the-aps/your-rights-and-responsibilities-as-an-aps-employee/code-of-conduct

Section 8 — Signatures

This section requires signatures from three people as outlined below.

8.1 — Organisation representative
The ERL Application Form must be signed by a person who has legal authority to sign on behalf of the applicant organisation (eg the CEO of the organisation, the director of the ART clinic or the department head at a university) – the person identified at Section 1.1.2.

8.2 — Principal supervisor
The ERL Application Form must be signed by the principal supervisor – the person identified at Section 1.2.1.1. If Joint Principal Supervisors are proposed then each one must sign the form.

8.3 — Chairperson of the HREC
The ERL Application Form must be signed by the chairperson(s) of the HREC(s) that considered the proposal – the person identified at Section 5.1.2. Before signing, the chairperson must check the validity of the information provided in Section 5.

Section 9 — Index of Supporting Information

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

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?		
Completed the application form?		
Ensured that the consent documents and process accurately reflect the project described in the application form?		
Completed the applicable consent checklist and included it with the application?		
Attached to the application the written evaluation prepared by the HREC?		
Arranged for the chairperson(s) of the HREC(s) that considered the original proposal to sign the application as the HREC chairperson (section 8)?		
Obtained all other signatures as outlined in section 8 of the application form?		
Proof-read the application and attachments?		
Attached all other relevant documents/approvals detailed in the application including CVs, consent documents, project description and relevant published articles?		
Submitted the application and all attachments to Embryo Research Licensing at embryo.research@nhmrc.gov.au?		