EMBRYO RESEARCH LICENSING COMMITTEE

Application for a Licence under section 20(1)(b) of the *Research Involving Human Embryos Act 2002*

This application form is to be used when seeking a licence under **section 20(1)(b)** of the *Research Involving Human Embryos Act 2002 (RIHE Act), which states:*

A person may apply to the NHMRC Licensing Committee for a licence authorising one or more of the following:

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

where:

human embryo *is defined in section 7 of the RIHE Act to mean a discrete entity that has arisen from either:*

> *(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or*
>
> *(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;*
>
> *and has not yet reached 8 weeks of development since the first mitotic division.*

For the avoidance of doubt, the Embryo Research Licensing Committee (ERLC) has determined that human embryoids that have the potential to develop up to, or beyond, the stage at which the primitive streak appears such as iBlastoids, meet the definition of an embryo under the RIHE Act under part (b) of that definition.

For further information or queries relating to this Licence Application Form, please contact Embryo Research Licensing: embryo.research@nhmrc.gov.au

Under the RIHE Act, it is an offence to use human 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 Embryo Research Licensing Committee, or the use is exempt from regulation.

IMPORTANT NOTE

- Applicants are advised to familiarise themselves with the requirements of the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002*.
- Applicants are 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 or addition information can be attached to the application and noted in the text box.
- Duplicate subsections (e.g. authorised persons & sites) as required and replace highlighted text with the required information.
- Complete applications should be saved as a .pdf and submitted by e-mail to Embryo Research Licensing at embryo.research@nhmrc.gov.au.

APPLICATION FOR A LICENCE UNDER SECTION 20(1)(b)

Application ID:
Application Date:

Section 1 — Applicant information

1.1 — Applicant Organisation

1.1.1 — Applicant organisation

Organisation name	
Street Address	
Postal 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 (if different to Organisational delegate)

Title	
Given names	
Surname	
Position	
Telephone number	
Mobile number	
Email address	

APPLICATION FOR A LICENCE UNDER SECTION 20(1)(b)

Application ID:
Application Date:

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	

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	

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

Attachment number for CV:

APPLICATION FOR A LICENCE UNDER SECTION 20(1)(b)

Application ID:
Application Date:

1.2.2 — Staff who will create or use embryos in research (duplicate this section as required)

Title	
Given names	
Surname	
Position	
Telephone number	
Mobile number	
Email address	
Role in proposed activity	

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 CVs:

APPLICATION FOR A LICENCE UNDER SECTION 20(1)(b)

Application ID:
Application Date:

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 — Organisation(s) from which the biological material for creating embryos will be obtained (duplicate this section if required)

Organisation name	
Postal address	
Contact name	
Position	
Telephone Number	
Email Address	

Nature of the biological material obtained	

APPLICATION FOR A LICENCE UNDER SECTION 20(1)(b)

Application ID:
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1.3.4 — Site (or sites) of consent 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	

Application ID:
Application Date:

Section 2 — Project Description

2.1 — Embryos to be used

Brief description of embryos	

2.2 — Proposed duration of licensed activity

2.3 — Title of proposed activity

2.4 — 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)

2.5 — 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.

2.6 — Number of *human embryos* likely to be created and justification for the number requested

Complete all applicable boxes in Section 2.6.

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

2.6.1 — Number of embryos likely to be necessary to achieve the goals of the proposed research activity

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

2.6.2 — Justification for the number of embryos created and used in licensable activity.

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

2.7 – Likelihood of significant advance in knowledge or improvement in technology as a result of the creation and/or use of embryos

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 creation or use of embryos proposed in the application.

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

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

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

SECTION 3 — Obtaining proper consent for the creation or use of embryos

ERLC must not issue a licence unless it is satisfied that appropriate protocols are in place to enable proper consent to be obtained before an 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* (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

3.1 — Overview of proper consent process

Provide a description and a flowchart which details how you will ensure proper consent has been obtained for all embryos created or used in research. Provide details of documents to be checked to ensure this and how you will ensure you notify the Licensing Committee that proper consent has been obtained before the creation and use of individual cell lines.

Application ID:
Application Date:

Section 4 — Compliance Issues

4.1 — Tracking system

Describe the tracking system that will be used to manage the creation of batches of *human embryos* and how the *human embryos* are used in the proposed activity. Maintenance of a tracking system that links the *human embryos* to activities under this licence and responsible persons will be a condition of a licence granted and NHMRC Inspectors will audit the system during their inspections. In your description, you should specifically include information on how you will comply with the 14 day rule.

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

Application ID:
Application Date:

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	
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	
Telephone number	
Mobile number	
Email address	
Relationship to Applicant 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:

Application ID:
Application Date:

Section 6 — CONFIDENTIAL COMMERCIAL INFORMATION

Does this application contain confidential commercial information?

☐ Yes ☐ No

6.1 — Identification of information

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

6.2 — Justification for treatment of information as confidential commercial information

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

Application ID:
Application Date:

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	

Application ID:
Application Date:

Section 8 — Index of supporting information

Provide an index of supporting documentation with attachment numbers

Attachment number	Attachment title