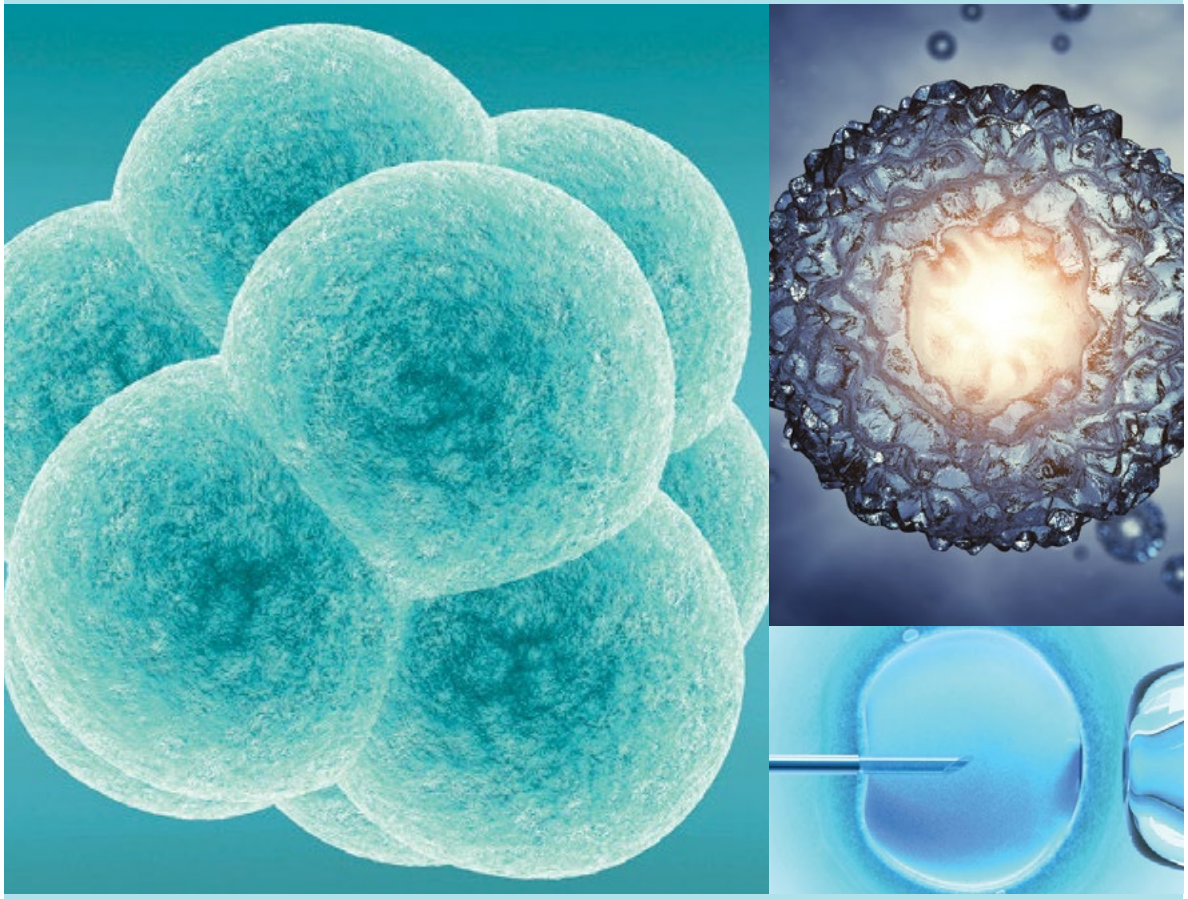
Australian Government
National Health and Medical Research Council

BUILDING
A HEALTHY
AUSTRALIA

NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia

For the period 1 September 2024 to 28 February 2025



NHMRC

Publication Details

Publication title:	NHMRC Embryo Research Licensing Committee: Report to the Parliament of Australia for the period 1 September 2024 to 28 February 2025
Published:	2025
Publisher:	National Health and Medical Research Council
NHMRC publication reference:	HC68
Online version:	www.nhmrc.gov.au/guidelines/publications
ISBN print:	2651-8554
ISBN online:	2651-8562
Suggested citation:	National Health and Medical Research Council (2025) NHMRC Embryo Research Licensing Committee: Report to the Parliament of Australia for the period 1 September 2024 to 28 February 2025. Canberra: National Health and Medical Research Council.

Contact us

To obtain information regarding NHMRC publications or submit a copyright request, contact:

E: communications@nhmrc.gov.au
P: (02) 6217 9000

Australian Government
National Health and Medical Research Council

NHMRC

The Hon Mark Butler MP
Minister for Health and Ageing
Parliament House
Canberra ACT 2600

Dear Minister

I am pleased to present to you the 45th biannual report from the National Health and Medical Research Council's (NHMRC) Embryo Research Licensing Committee (ERLC) which, in accordance with section 19(3) of the *Research Involving Human Embryos Act 2002* (RIHE Act), reports on the operation of the RIHE Act and the licences issued under it.

This report is for the period 1 September 2024 to 28 February 2025 and describes the activities ERLC has undertaken during this reporting period, including associated monitoring and compliance activities.

ERLC met twice during this reporting period and considered two applications to vary existing general licence conditions. On 7 December 2024, 2 general licences expired and as of 28 February 2025 there were 2 active general licences under the RIHE Act.

ERLC is the responsible authority for licensing research and specialised training in mitochondrial donation techniques, and licensing and overseeing a suitable IVF clinic to deliver mitochondrial donation as part of a clinical research trial. There were no mitochondrial donation licences issued or active during the reporting period.

Louise Johnson
Chairperson
NHMRC Embryo Research Licensing Committe
22 May 2025

Table of contents

Introduction

Legislative framework

The Commonwealth *Research Involving Human Embryos Act 2002* (the RIHE Act) and *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) were introduced to address community concerns, including ethical concerns, about scientific developments in relation to human reproduction and the use of human embryos in research activities.

Administered by the Embryo Research Licensing Committee (ERLC) of the National Health and Medical Research Council (NHMRC) these Acts establish a national human embryo research regulatory framework. They prohibit certain practices, such as human cloning, and regulate the uses of excess assisted reproductive technology (ART) embryos, the creation or uses of other human embryos created through processes other than fertilisation and the practice of permitted mitochondrial donation techniques in Australia. There are strong penalties for non-compliance with the legislation.

In line with section 29 of the RIHE Act, ERLC maintains a database containing information about licences issued. This database can be accessed on the NHMRC website at www.nhmrc.gov.au.

Reporting to Parliament

Section 19(3) of the RIHE Act requires ERLC to table twice yearly reports in either House of Parliament on or before 30 June and 31 December each year and at any other time as required by either House of Parliament. The reports must include information about the activities of ERLC, operation of the RIHE Act and about licences issued under this Act.

This is the 45th Report to the Parliament of Australia by ERLC and covers the period 1 September 2024 to 28 February 2025.

Further information

Further information about this report and the issue of licences can be obtained by contacting:

Director, Research Quality and Equity
Research Quality and Advice Branch
NHMRC
GPO Box 1421
CANBERRA ACT 2601

Telephone: 02 6217 9000
Email: embryo.research@nhmrc.gov.au
Website: www.nhmrc.gov.au

Membership of ERLC

ERLC Members are appointed by the responsible Minister, according to the process prescribed in the RIHE Act. Appointments are on a part-time basis for a period not exceeding three years, with Members eligible for reappointment.

The expertise of each Member is prescribed in the RIHE Act. The Committee includes individuals with expertise in research ethics, research, assisted reproductive technology, law, consumer health and disability, the regulation of assisted reproductive technology, and embryology. It also includes a Cross-member with the Australian Health Ethics Committee of NHMRC.

Appointments for the 2024–2027 triennium commenced on 23 September 2024 and will conclude on 30 June 2027. The Membership of ERLC is detailed at **Appendix A**.

Functions

The functions of ERLC are to:

- assess and determine applications for general and mitochondrial donation licences to conduct research involving human embryos
- issue (subject to conditions) or not issue such licenceses
- monitor licensed activities to ensure compliance with the legislation and take enforcement action as necessary
- maintain an accessible database containing information about licences issued
- report to the Parliament of Australia on the functions of ERLC, the operation of the RIHE Act and the licences issued under this Act
- perform such other functions as are conferred on it by the RIHE Act or any other relevant law.

Operation of ERLC

Committee meetings

During the reporting period ERLC conducted 1 formal meeting (28 October 2024) and held 1 workshop over 2 days to consider additional licensing matters (3–4 February 2025).

New licences issued

No licences were issued during the reporting period.

Variations to existing licences

The RIHE Act empowers ERLC to vary any licence issued under the Act. Variations to licences may either be requested by the licence holder or initiated by ERLC. Variations may be of an administrative nature (e.g. change to site address) or may relate to aspects of the authorised activities (e.g. number of embryos used).

During the reporting period ERLC varied 2 licences. Further information is at **Appendix B**.

Expiry of licences

Two general research licences expired in the reporting period (refer to table below). The final activity reports for these licences are included in this report.

Licence number	Licence holder	Expiry Date
309718	Genea Limited	7 December 2024
309719	Genea Limited	7 December 2024

Progress of licensed activities

Licence holder reports

Licence holders are required to report every 6 months on the progress of their licensed activities. The following reports have been received from the licence holders.

Current licences

Licence 309727 – Melbourne IVF	
Licence number	309727
Licence holder	Melbourne IVF Pty Ltd
Licence title	Comprehensive chromosomal analysis of human preimplantation embryos.
Progress of the licensed activity this reporting period	During this reporting period, identification and recruitment of eligible patients continued. One patient provided consent to donate one embryo to the project, bringing the total to 18 patients and 86 embryos. To date, 8 embryos from one patient have been removed from storage and warmed for the project. Two of those embryos did not develop to a stage that could be used and were discarded. The remaining 6 embryos were used for the project. All other embryos remain in storage.

Licence 309729 – Monash University	
Licence number	309729
Licence holder	Monash University
Licence title	The generation and study of a novel *in-vitro* model of human blastocysts ('iBlastoids')
Progress of the licensed activity this reporting period	During this period, we made progress in optimising the conditions for iBlastoid/blastoid formation and explored alternative approaches. Since the licence's inception, 17,636 iBlastoids/Blastoids have been generated, including 6,704 during this reporting period. Of these, 4,520 structures were fixed for immunofluorescence analysis, 2,064 were dissociated into cells and processed for flow cytometry applications, and the remaining 120 were lysed for molecular studies. By testing various conditions, we identified markers, such as VIMENTIN, CD70, and TROP-2, helping us better classify these cell types. These findings strengthen our ability to model early human development using stem cell-based systems, providing valuable insights into processes such as lineage specification.

Expired licences (during the reporting period)

Licence 309718 – Genea Limited	
Licence number	309718
Licence holder	Genea Limited
Licence title	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device
Progress of the licensed activity this reporting period	The Gavi system was developed by Genea's research division Biomedx, which validated the system for human clinical use using the eggs and embryos donated to Genea under this licence. The Gavi system has been commercialised and is now available for purchase by fertility clinics around the world. Genea Biomedx now exists as a separate company and the intellectual property and any revenue for the Gavi system sits with Genea Biomedx. www.geneabiomedx.com This licence closed on 7 December 2024.

Licence 309718 – Genea Limited	
Licence number	309718
Licence holder	Genea Limited
Licence title	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device
Progress of the licensed activity this reporting period	The Gavi system was developed by Genea's research division Biomedx, which validated the system for human clinical use using the eggs and embryos donated to Genea under this licence. The Gavi system has been commercialised and is now available for purchase by fertility clinics around the world. Genea Biomedx now exists as a separate company and the intellectual property and any revenue for the Gavi system sits with Genea Biomedx. www.geneabiomedx.com This licence closed on 7 December 2024.

Licensed use of excess ART embryos

The following table shows the use of excess ART embryos under licence, as at 28 February 2025.

Current research licences

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 28 February 2025	Embryos used during the reporting period
309727	Melbourne IVF Pty Ltd	Comprehensive chromosomal analysis of human preimplantation embryos	100[a]	6[b]	0

Expired licences (during the reporting period)

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 28 February 2025	Embryos used during the reporting period
309718	Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	345	259	0
309719	Genea Limited	Use of excess ART embryos for the development of improved IVF culture media	640	58	0

a Maximum of 200 excess ART embryos may be removed from cryostorage and thawed to obtain the 100 embryos for the authorised activity.
b 8 embryos thawed with 2 not viable for use (refer footnote a)

Licensed use of human eggs

The following table shows the use of human eggs under licence, as at 28 February 2025.

Expired licences (during the reporting period)

Licence number	Licence holder	Licence title	Eggs authorised to be used under licence	Eggs used in licensed activity up to 28 February 2025	Eggs used during the reporting period
309718	Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	1,000	407	0

Licensed use of 'other embryos'

The following table shows the use[c] of 'other embryos' under licence, as at 28 February 2025.

Current research licences

Licence number	Licence holder	Licence title	'Other embryos' authorised to be used under licence[d]	'Other embryos' used in licensed activity up to 28 February 2025.	'Other embryos' used during the reporting period
309729	Monash University	The generation and study of a novel *in-vitro* model of human blastocysts ('iBlastoids')	117,010* *initially assessed as showing basic morphological features of an iBlastoid	17,636	6,704

c Use is defined in the RIHE Act as: "***use*** includes develop, or development, as the case requires"; for licence 309729 this includes the creation of an iBlastoid for the activities authorised under that licence.

Monitoring compliance with the legislation

ERLC is committed to ensuring that individuals and licence holder organisations comply with both the RIHE Act and the PHCR Act.

The legislation establishes a monitoring and compliance framework, which involves the appointment of inspectors and the conduct of a range of monitoring and compliance activities. Further information about the monitoring and compliance activities NHMRC undertakes on behalf of ERLC can be found on the NHMRC website at: www.nhmrc.gov.au/research-policy/embryo-research-licensing.

Monitoring activities

NHMRC inspectors conducted one on-site licence inspection during the reporting period and undertook monitoring activities to facilitate and monitor end of licence activities for expiring licences.

Throughout the period inspectors also continued to monitor information provided by licence holders through legislated six-monthly reports to ERLC and to correspond with licence holders as needed.

Communication and awareness

ERLC considers that providing opportunities for communication and awareness between stakeholders assists with compliance under the legislation and with individual licence conditions.

General information for both applicants and licence holders can be accessed on NHMRC's website at www.nhmrc.gov.au. The NHMRC website contains more information about embryo research licensing, including copies of the RIHE and PHCR Acts, standard conditions that apply to all licences (unless a particular standard condition is specifically excluded by the Special conditions for a licence), application forms and detailed instructions, checklists, and other explanatory materials.

Individuals and organisations considering applying for a licence under the RIHE Act are strongly encouraged to contact ERLC, noting that NHMRC responds to all queries received.

Appendix A: 2024–2027 Embryo Research Licensing Committee

Ms Louise Johnson, Victoria (Chair)
A person with expertise in the regulation of assisted reproductive technology

Professor Jackie Leach Scully, New South Wales
A member of the Australian Health Ethics Committee (AHEC)

Professor Lynn Gillam AM, Victoria
A person with expertise in research ethics

Professor Sarah Robertson AO, South Australia
A person with expertise in a relevant area of research

Professor Roger Hart, Western Australia
A person with expertise in assisted reproductive technology

Professor Jane Nielsen, Tasmania
A person with expertise in a relevant area of law

Ms Emma Turner, Victoria
A person with expertise in consumer health issues relating to disability and disease

Ms Cal Volks, Victoria
A person with expertise in consumer issues relating to assisted reproductive technology

Professor Patrick Tam, New South Wales
A person with expertise in embryology

Appendix B: Variations to licences

During the reporting period, ERLC varied licences as follows:

Licence No.	Organisation	Date of variation	Brief description of variation
309729	Monash University	14 November 2024	Removed one 'Authorised Person'
309727	Melbourne IVF	28 October 2024	Added one 'Authorised Person'

Appendix C: Glossary of Terms

Term	Description
AHEC	Australian Health Ethics Committee (a Principal Committee of the National Health and Medical Research Council).
Application for a licence	Application form for a licence to conduct research activities permitted under section 20(1) of the *Research Involving Human Embryos Act 2002*.
ART	Assisted reproductive technology.
ART embryo	A human embryo that was created by assisted reproductive technology for use in the assisted reproductive technology treatment of a woman.
Blastocyst	A 5-to-7-day-old embryo that has an outer layer of cells and a fluid filled cavity in which there is a cluster of cells called the inner cell mass.
Chromosomal analysis	Test to look at the number of chromosomes present in a sample of cells, and to identify genetic abnormalities as the cause of a condition or disease.
Cryostorage	The storage of biological material (e.g., cells, tissues, or organs) at ultralow or freezing temperatures to preserve them for future use.
Embryonic stem cell	An undifferentiated cell that is a precursor to many different cell types, obtained from a preimplantation embryo, usually at blastocyst stage.
ERLC	The Embryo Research Licensing Committee of the National Health and Medical Research Council.
Excess ART embryo	An ART embryo that is excess to the needs of the woman for whom it was created and her spouse (if any) at the time the embryo was created, as determined in writing by section 9 of the *Research Involving Human Embryos Act 2002*.
Gamete	A human sperm or egg (ovum or oocyte).
HREC	A human research ethics committee.
Human embryo clone	A human embryo that is a genetic copy of another living or dead human.
iBlastoid	Human embryos (and human embryo clones) generated through the reprogramming of adult skin cells in-vitro, into a three-dimensional cluster of cells that resemble a blastocyst and has the potential to develop up to the stage at which the primitive streak appears.

Term	Description
Information Exchange Visit	A pre-arranged visit by NHMRC inspectors to provide information about the legislation to interested stakeholders.
Inspection	An inspection of records, documents, and premises to ensure compliance with licence conditions and the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002.*
IVF	*In vitro* fertilisation.
Mitochondrial donation	Mitochondrial donation is an assisted reproductive technology that, when combined with in vitro fertilisation (IVF), has the potential to allow women whose mitochondria would predispose their potential children to mitochondrial disease, to have a biological child who does not inherit that predisposition. There are a number of different mitochondrial donation techniques; each involves combining the nuclear DNA from a male and a female with healthy mitochondrial DNA from a donor egg to create an embryo.
Monitoring and compliance activities	Activities conducted to monitor and assess compliance requirements with licence conditions, under the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002.*
NHMRC	National Health and Medical Research Council.
Oocyte	An immature egg cell.
Other embryos	Other embryos is the term used in the *Research Involving Human Embryos Act 2002* to refer to human embryos created by processes other than fertilisation of a human egg by a human sperm.
Preimplantation genetic diagnosis	A procedure used prior to implantation to detect serious genetic conditions, diseases, or abnormalities, to which the gamete providers are known to be at risk, to carry or to be predisposed.
Primitive streak	An elongated band of cells that forms along the axis of a developing fertilised egg on day 15 of human development, marking the start of gastrulation.
Proper Consent	Consent obtained in accordance with the *Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research 2017*, issued by NHMRC.
Skin fibroblasts	A connective-tissue cell that secretes molecular collagen proteins into the extracellular matrix to form the structural framework of dermal tissue.
Somatic Cell Nuclear Transfer (SCNT)	A laboratory technique used to create a human embryo clone involving removing the nucleus of a human egg and replacing it with the genetic material from a somatic cell (such as a skin cell or fibroblast) or stem cell line.
Zygote	A cell formed by the fertilisation between two gametes.

nhmrc.gov.au