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NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia
For the period 1 March to 31 August 2025

NHMRC

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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 46th 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 March to 31 August 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 2 applications to vary the conditions of existing general licences. As of 31 August 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
Chair
NHMRC Embryo Research Licensing Committe
22 October 2025

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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 46th Report to the Parliament of Australia by ERLC and covers the period 1 March to 31 August 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 Minister for Health and Ageing 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.

During this reporting period, the Minister for Health and Ageing accepted the resignation of the Member with expertise in a relevant area of research. The Minister appointed a replacement Member on 29 July 2025 in accordance with the provisions of the RIHE Act.

The Membership of ERLC is detailed at **Appendix A**.

Functions

The functions of ERLC are prescribed in the RIHE Act:

- assess and determine applications for general and mitochondrial donation licences to conduct research involving human embryos
- issue (subject to conditions) or not issue such licences
- 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 conferred on it by the RIHE Act or any other law.

Operation of ERLC

Committee meetings

During the reporting period ERLC conducted one formal meeting (1 April 2025), held one workshop to consider additional licensing matters (28 April 2025) and considered 3 other matters out of session.

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**.

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.

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. Two patients provided their consent to donate their embryos to the project, bringing the total to 20 patients with 92 embryos. To date, eight 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 six 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 reporting period, 9,833 iBlastoids/Blastoids were generated, bringing the total to 27,469 since the licence's inception. The focus was on improving the formation of iBlastoid/ Blastoids, through adjusting the culture conditions, such as the timing of media changes, and strategies to reduce stress on the cells. Overall, these results highlight that refinements in both the extracellular environment and temporal cues during the early stages of cell aggregation are important for optimal iBlastoid generation.

Licensed use of excess ART embryos

The following table shows the use of excess ART embryos under licence, as at 31 August 2025.

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 31 August 2025	Embryos used during the reporting period
309727	Melbourne IVF Pty Ltd	Comprehensive chromosomal analysis of human preimplantation embryos	100[a]	6[b]	0

Licensed use of 'other embryos'

The following table shows the use[c] of 'other embryos' under licence, as at 31 August 2025.

Licence number	Licence holder	Licence title	'Other embryos' authorised to be used under licence	'Other embryos' used in licensed activity up to 31 August 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	27,469	9,833

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).

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 undertook activities to monitor compliance with varied licensed conditions during the reporting period.

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 (to 1 June 2025)
A person with expertise in a relevant area of research

Professor Josephine Bowles, Queensland (from 29 July 2025)
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
309727	Melbourne IVF	1 April 2025	Amendment of Specified Sites (with transition period) Extension to period of licence Removal of Authorised Person
309729	Monash University	5 May 2025	Extension to period of licence

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.
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.*

Term	Description
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.

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