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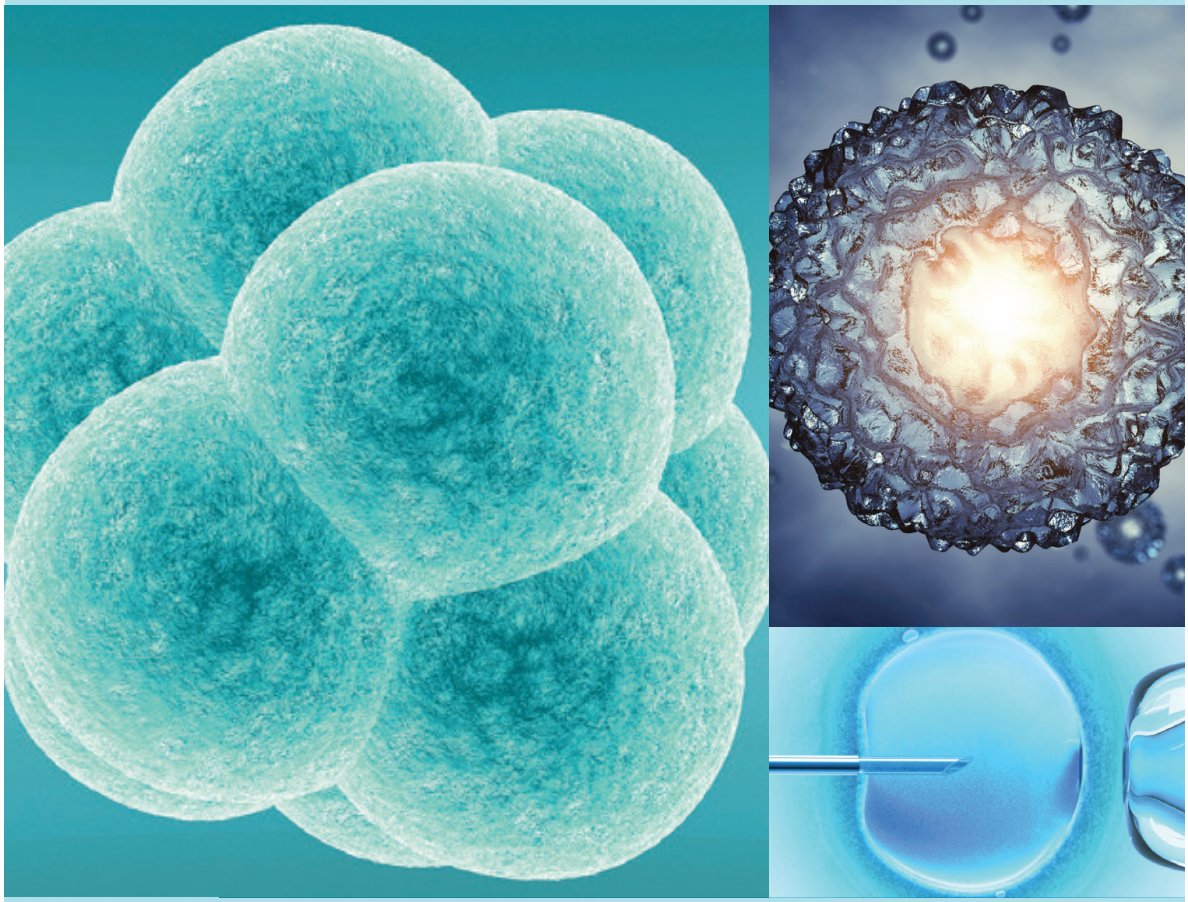
NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia

For the period 1 September 2021 to 28 February 2022



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Australian Government
National Health and Medical Research Council

NHMRC

The Hon Mark Butler MP
Minister for Health and Aged Care
Parliament House
CANBERRA ACT 2600

Dear Minister

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

This report covers the period 1 September 2021 to 28 February 2022 and describes the activities the Committee has undertaken, including associated monitoring and compliance activities. The Committee met twice during this reporting period and considered a range of licensing matters detailed in this report.

Additionally, with NHMRC's assistance, the Committee progressed development of a licensing framework to meet its responsibilities under the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* that is expected to come into effect on 2 October 2022. The Committee's responsibilities will include licensing research and specialised training in mitochondrial donation techniques and licensing and overseeing a suitable IVF clinic to deliver mitochondrial donation to couples as part of a clinical research trial.

Yours sincerely

Professor Dianne Nicol
Chair, NHMRC Embryo Research Licensing Committee
6 June 2022

Telephone
+6102 6217 9000
16 Marcus Clarke Street,
Canberra ACT 2601

info@nhmrc.gov.au
nhmrc.gov.au

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Introduction

Legislative framework

The Commonwealth *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) and *Research Involving Human Embryos Act 2002* (RIHE Act) were developed to address community concerns, including ethical concerns, about scientific developments in relation to human reproduction and the use of human embryos in research activities. The legislation prohibits human cloning for reproductive purposes and a range of other practices relating to reproductive technology. It also regulates research activities that involve the use of human embryos created by assisted reproductive technology (ART) or by other means. There are strong penalties for noncompliance with the legislation.

The RIHE Act established the Embryo Research Licensing Committee of the National Health and Medical Research Council (the NHMRC Licensing Committee) as a Principal Committee of NHMRC. One of the functions of the NHMRC Licensing Committee is to consider applications for licences to conduct research involving human embryos. As required under section 29 of the RIHE Act, the NHMRC Licensing Committee maintains a publicly available database containing information about licences issued. This database can be accessed on the NHMRC website at www.nhmrc.gov.au.

In April 2002 and again in April 2007, the Council of Australian Governments agreed to introduce nationally consistent legislation to support the regulatory framework. Information about the implementation of complementary state and territory legislation is included at **Appendix B** to this report.

The Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 was passed by the Parliament of Australia in March 2022. The Act will come into effect on 2 October 2022, unless proclaimed earlier. The Act amends the PHCR and RIHE Acts to allow mitochondrial donation (an assisted reproductive technology technique that could help prevent certain rare mitochondrial diseases) to be used in research and training activities and for human reproductive purposes. The NHMRC Licensing Committee will be the responsible authority for the new licensing scheme, administering three new licences in the initial stage of implementation.

Reporting to Parliament

Section 19(3) of the RIHE Act requires the NHMRC Licensing Committee 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 operation of the RIHE Act and about licences issued under this Act.

This is the thirty-ninth Parliamentary Report of the NHMRC Licensing Committee, which covers the period 1 September 2021 to 28 February 2022.

Further information

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

Embryo Research Team
National Health and Medical Research Council
GPO Box 1421
CANBERRA ACT 2601

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

Membership of the NHMRC Licensing Committee

The NHMRC Licensing Committee was established in May 2003 under the RIHE Act. The nine-member NHMRC Licensing Committee is responsible for making statutory decisions as outlined in the RIHE Act.

Members are appointed by the Minister for Health, 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.

NHMRC Licensing Committee appointments for the 2021–2024 NHMRC triennium commenced on 30 September 2021.

The membership of the NHMRC Licensing Committee is detailed at **Appendix A**.

Functions

Established as a Principal Committee of NHMRC, the functions of the NHMRC Licensing Committee are to:

- consider applications for licences to conduct research involving human embryos
- issue (subject to conditions) or not issue such licences
- maintain a publicly available database containing information about licences issued
- monitor licensed activities and ensure compliance with the legislation through the appointment of inspectors and take necessary enforcement action, such as cancelling or suspending licences
- report to the Parliament of Australia on 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 the NHMRC Licensing Committee

Committee meetings

During the reporting period the NHMRC Licensing Committee met on 30 November and 17 December 2021.

Consideration of licence applications

NHMRC's Licensing Committee commenced its assessment of a new licence application received in November 2021.

New licences issued

NHMRC's Licensing Committee issued a conditional offer of licence in relation to an application received in a previous reporting period.

Variations to existing licences

The RIHE Act empowers the NHMRC Licensing Committee to vary a licence issued under the Act. Variations to licences may either be requested by the licence holder or initiated by the NHMRC Licensing Committee. 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 the NHMRC Licensing Committee approved one variation to a licence, initiated by the licence holder, as follows:

Licence No.	Organisation	Date of variation	Brief description of variation
309718	Genea Limited	30 November 2021	Licence extension to 7 December 2024

Progress of licensed activities

Licence holder reports

Licence holders are required to report every six months on the progress of licensed activities. The following reports on the progress of licensed activities are provided here as received from the licence holders.

Current licences

Licence number	**309702B**
Licence holder	Genea Limited
Licence title	Development of methods for preimplantation genetic and metabolic evaluation of human embryos
Progress of licensed activity to date	No work has been carried out in this reporting period.

Licence number	**309703**
Licence holder	Genea Limited
Licence title	Development of human embryonic stem (ES) cells
Progress of licensed activity to date	Under this licence we have derived a total of thirty (30) cell lines, four of which are karyotypically abnormal. Cell lines from this licence have been registered at the National Institutes of Health (NIH) registry and have been approved by the Steering Committee of the United Kingdom (UK) Stem Cell Bank for research use in the UK. Cell lines are available to researchers worldwide for basic disease research and drug development projects. Various distribution services aid in this process.

Licence number	**309710**
Licence holder	Genea Limited
Licence title	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known serious monogenic conditions
Progress of licensed activity to date	Under this licence, a total of forty-six (46) affected stem cell lines have been derived, four of which are karyotypically abnormal. Cell lines from this licence have been registered at the National Institutes of Health (NIH) registry and have been approved by the Steering Committee of the UK Stem Cell Bank for research use in the UK. Cell lines are available to researchers worldwide for basic disease research and drug development projects. Various distribution services aid in this process.

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 licensed activity to date	Over the lifetime of the project, clinically unsuitable abnormally fertilised eggs and excess-declared ART blastocysts have been used to develop an automated vitrification instrument (Gavi) for freezing of oocytes, zygotes/cleavage stage and blastocyst stage embryos. After the product development process, the instrument and associated consumables are CE marked[1] products and are commercially distributed across several regions. The Gavi system has approved protocols for freezing of oocytes, zygotes/cleavage stage and blastocyst stage embryos. Further optimisations for the different developmental stages may be required as post market surveillance data is continuously monitored and commercial success ascertained.

Licence number	**309719**
Licence holder	Genea Limited
Licence title	Use of excess ART embryos for the development of improved IVF culture media
Progress of licensed activity to date	The current projects are centred around developing new products for inclusion within the Gems media suite. These projects, which vary widely depending on the product in question, are ongoing; some having utilised excess ART embryos already and some are progressing to a stage where they are likely to do so. The use of clinically excess ART embryos in product development is essential. Animal models play a large part in progressing new media, but as their response is not always a true representation of how human embryos will respond, it is important to have a stage between animal model experiments and clinical use, improving confidence in the new products before subjecting patients to those new innovations.

Licence number	**309726**
Licence holder	Genea Limited
Licence title	Use of excess ART embryos for training in an alternate biopsy method (day five hatch and biopsy)
Progress of licensed activity to date	Since the issue of the licence in June 2019 the consent process has been initiated. At this time licensed activity has not commenced due to the restrictions that COVID-19 has had on staff sharing workspaces, impacting training.

1 CE mark affirms compliance with the legislation applicable in the European Economic Area.

Licensed use of excess ART embryos

The following tables show the use of excess ART embryos under licence, as at 28 February 2022.

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 2022	Embryos used during the reporting period
309702B	Genea Limited	Development of methods for preimplantation genetic and metabolic evaluation of human embryos	220	58	0
309703	Genea Limited	Development of human embryonic stem (ES) cells	300 (plus up to 20 inner cell masses which may be transferred from 309702A or 309702B)	249 (plus 12 embryos first used in 309702A and then transferred to 309703)	0
309710	Genea Limited	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known serious monogenic conditions	500	304	0
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
Total for current research licences			**2005**	**928**	**0**

Current training licences

Licence number	Licence holder	Licence title	Embryos per trainee authorised to be used under licence[2]	Number of active authorised trainees at 28 February 2022	Embryos used in licensed activity up to 28 February 2022 (total all trainees)[3]	Embryos used during the reporting period (total, all trainees)
309726	Genea Limited	Use of excess ART embryos for training in an alternate biopsy method (day five hatch and biopsy)	25	15	0	0
Total for current training licences			**25**	**15**	**0**	**0**

Licensed use of human eggs or creation of other embryos

The following tables show the use of human eggs or creation of other embryos under licence, as at 28 February 2022. Other embryos is the term used in the RIHE Act to refer to human embryos created by processes other than fertilisation of a human egg by a human sperm.

Current licences

Licence number	Licence holder	Licence title	Eggs authorised to be used under licence	Eggs used in licensed activity up to 28 February 2022	Eggs used during the reporting period
309718	Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	1000	407	0
Total for current licences			**1000**	**407**	**0**

2 The Special Conditions of each licence permit this number of embryos to be removed from cryostorage and thawed in order to obtain a smaller number of suitable embryos for the training activity.

3 Reflects the total number of embryos removed from cryostorage across the period of the licence, noting that the total number of embryos authorised for use under each licence is dependent on the total number of authorised trainees and fluctuates as authorised trainees are added or removed from the licence.

Monitoring compliance with the legislation

NHMRC 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 Embryo Research Monitoring and Compliance Framework can be found on the NHMRC website at www.nhmrc.gov.au/research-policy/embryo-research-licensing.

Monitoring activities

NHMRC inspectors did not conduct any on-site licence inspections or hold any monitoring discussions during the reporting period.

During September 2021, it was identified that a minor breach occurred, with the late receipt of the March to August 2021 Licensed Activity report for licence holder 309726.

A review of the explanation for the late submission and the report found that, whilst a technical breach of Licence Condition 3001 did occur, the breach did not meet the requirements for an offence under the RIHE Act.

Throughout the period, inspectors continued to monitor information provided by licence holders through legislated 6-monthly reports to the NHMRC Licensing Committee and to correspond with licence holders as needed.

Communication and awareness

The NHMRC Licensing Committee has published an information kit that can be accessed on NHMRC's website at www.nhmrc.gov.au. Researchers and other interested people can contact the committee by e-mail. The committee responds to all queries received.

Information exchange visits

No information exchange visits were conducted during this reporting period.

Appendix A: Membership of the NHMRC Licensing Committee

Members of the NHMRC Licensing Committee for the 2021–2024 triennium are:

Professor Dianne Nicol, Tasmania (Chair)

A person with expertise in a relevant area of law

Associate Professor Bernadette Richards, South Australia

A member of the Australian Health Ethics Committee (AHEC)

Professor Lynn Gillam AM, Victoria

A person with expertise in research ethics

Professor Sarah Robertson, South Australia

A person with expertise in a relevant area of research

Professor Stephen Robson, Australian Capital Territory

A person with expertise in assisted reproductive technology

Dr Carol Wicking, Queensland

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

Ms Louise Johnson, Victoria

A person with expertise in the regulation of assisted reproductive technology

Professor Patrick Tam, New South Wales

A person with expertise in embryology

Appendix B: Corresponding state and territory legislation

Following the passage of the *Prohibition of Human Cloning and the Regulation of Human Embryo Research Amendment Act 2006*, embryo research in Australia must comply with both Commonwealth and corresponding state and territory legislation. Victoria, New South Wales, Tasmania, Queensland, the Australian Capital Territory and South Australia have all passed amending complementary legislation. The relevant legislation for each state and territory has been declared to be a corresponding law by the Minister responsible for the *Research Involving Human Embryos Act 2002*.

The relevant state and territory legislation is as follows:

Victoria

Research Involving Human Embryos Act 2008

New South Wales

Research Involving Human Embryos (New South Wales) Act 2003

Tasmania

Human Embryonic Research Regulation Act 2003

Queensland

Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003

South Australia

Research Involving Human Embryos Act 2003

Australian Capital Territory

Human Cloning and Embryo Research Act 2004

Appendix C: Glossary of Common 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.
COAG	The Council of Australian Governments was the peak intergovernmental forum in Australia. The members of COAG were the Prime Minister, state and territory Premiers and Chief Ministers and the President of the Australian Local Government Association.
Compliance	Ensuring that the requirements of the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002* are met.
Embryonic stem cell	An undifferentiated cell that is a precursor to many different cell types, obtained from a preimplantation embryo, usually at blastocyst stage.
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.
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.*
Investigation	An inquiry into a suspected breach of the legislation with the aim of gathering evidence. An investigation may be initiated as a consequence of monitoring by NHMRC inspectors, self-reporting or third-party reporting.
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.

Term	Description
Monitoring	Activities conducted to assess the level of compliance with licence conditions, the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002.*
NHMRC	National Health and Medical Research Council.
NHMRC Licensing Committee	The Embryo Research Licensing Committee of the National Health and Medical Research Council.
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.
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 the NHMRC.
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.

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