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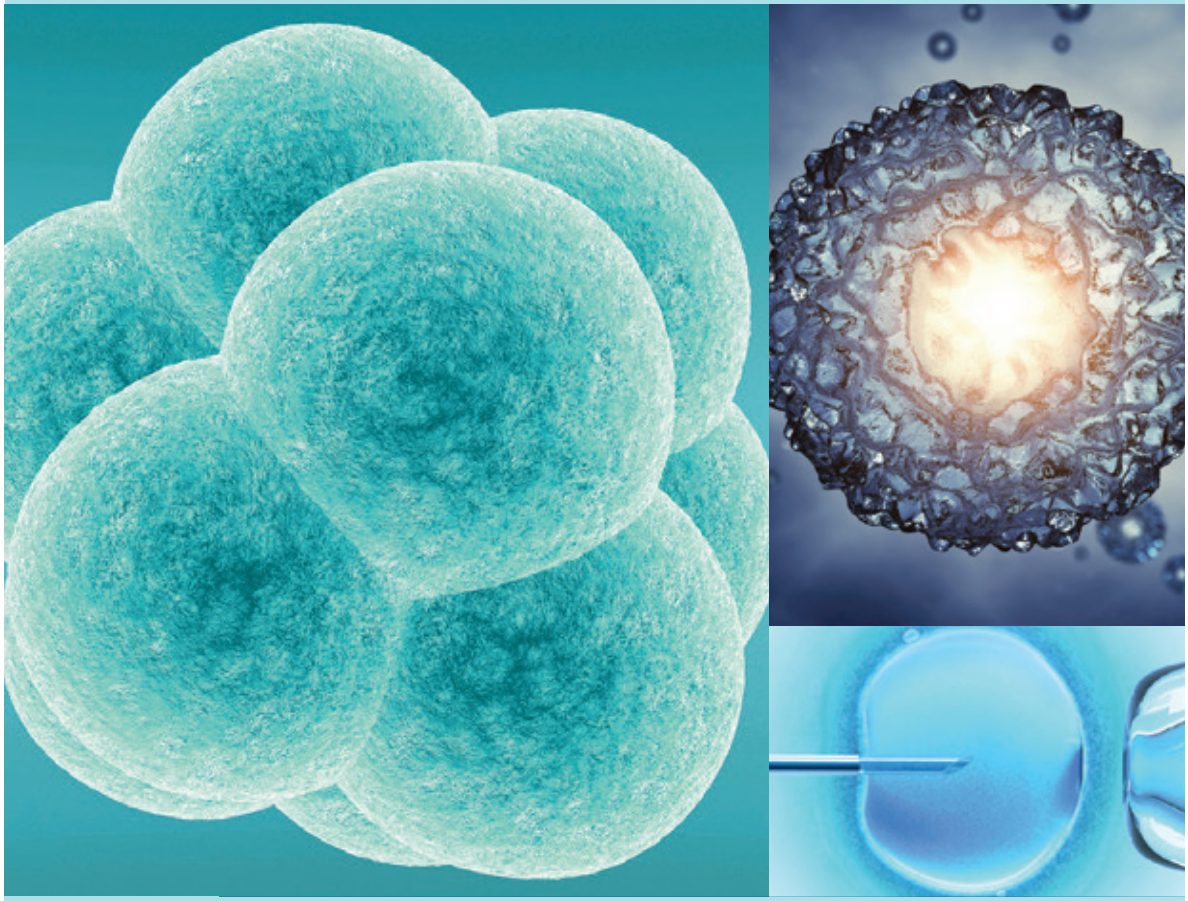
NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia

For the period 1 March to 31 August 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 40th biannual report from the National Health and Medical Research Council (NHMRC) Embryo Research Licensing Committee (the NHMRC Licensing Committee) which, in accordance with section 19(3) of the *Research Involving Human Embryos Act 2002* (the 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 2022 and describes the activities the NHMRC Licensing Committee has undertaken during this reporting period, including associated monitoring and compliance activities.

The NHMRC Licensing Committee met three times during this reporting period and issued one licence for the use of excess assisted reproductive technology (ART) embryos in research. The NHMRC Licensing Committee also continued its assessment of a licence application received in a previous reporting period and issued variations to four existing licences.

Additionally during this period, the NHMRC Licensing Committee progressed development of the licensing framework to deliver its responsibilities under the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022.* The Act amends the RIHE Act and the *Prohibition of Human Cloning for Reproduction Act 2002* to enable the staged introduction of mitochondrial donation into Australian clinical IVF practice. Under the framework, the NHMRC Licensing Committee will be responsible 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.

Yours sincerely

Professor Dianne Nicol
Chairperson, NHMRC Embryo Research Licensing Committee
4 November 2022

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Table of contents

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 non-compliance 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 former 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 C to this report.

The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* came into effect on 1 October 2022. The Act amends the PHCR and RIHE Acts to allow mitochondrial donation (an assisted reproductive technology technique that might help prevent certain rare mitochondrial diseases) to be used in research and training activities and for human reproductive purposes subject to the outcome of clinical trials. The NHMRC Licensing Committee is the responsible authority for the new mitochondrial donation licensing framework and will administer 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 40th Parliamentary Report of the NHMRC Licensing Committee, which covers the period 1 March to 31 August 2022.

Further information

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

Director, Governance, Regulation and Secretariat Support
Research Quality and Priorities 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 the NHMRC Licensing Committee

The NHMRC Licensing Committee was established in May 2003 under the *Research Involving Human Embryos Act 2002* (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 and Aged Care, 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 the 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 15 and 22 March and 14 June 2022.

Consideration of licence applications

The NHMRC Licensing Committee continued its assessment of one application received in a previous reporting period.

New licences issued

One licence was issued in the reporting period. On 15 August 2022, the NHMRC Licensing Committee issued Licence 309727 to Melbourne IVF Pty Ltd. The licence permits Melbourne IVF Pty Ltd to culture and biopsy excess ART embryos to assess the concordance between chromosomal analysis of the embryo and the media the embryo was cultured in.

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 varied four licences. These variations were initiated by the licence holder and the NHMRC Licensing Committee.

Further information about variations to existing licences approved during the reporting period is at Appendix B.

Progress of licensed activities

Licence holder reports

Licence holders are required to report every six months on the progress of their 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 UK Stem Cell Bank for research use in the United Kingdom (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 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[1] marked 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 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. Licensed activity did not commence due to the restrictions that COVID has had on staff sharing workspaces, impacting training. This licence is now due for closure on 5 December 2022.

Licence number	**309727**
Licence holder	Melbourne IVF Pty Ltd
Licence title	Comprehensive chromosomal analysis of human preimplantation embryos
Progress of licensed activity to date	The licence was issued 15 August 2022. There has been no activity during this reporting period.

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 31 August 2022.

Current research licences

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 31 August 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
309727	Melbourne IVF Pty Ltd	Comprehensive chromosomal analysis of human preimplantation embryos	100 (maximum of 200 excess ART embryos may be removed from cryostorage and thawed to obtain the 100 embryos)	0	0
Total for current research licences			**2,105**	**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 31 August 2022	Embryos used in licensed activity up to 31 August 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 31 August 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 31 August 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	1,000	407	0
Total for current licences			**1,000**	**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

The 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. Monitoring discussions were held with one licence holder following their notification of licence closure.

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 or telephone. 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, Queensland

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: Variations to licences

During the reporting period, the NHMRC Licensing Committee varied licences as follows:

Licence No.	Organisation	Date of variation	Brief description of variation
309702B	Genea Limited	13 April 2022	Licence extension to 2 June 2022
		31 May 2022	Licence extension to 2 December 2022 and introduction of supplementary reporting
309703	Genea Limited	13 April 2022	Licence extension to 2 June 2022
		31 May 2022	Licence extension to 2 December 2022 and introduction of supplementary reporting
309710	Genea Limited	13 April 2022	Licence extension to 2 June 2022
		31 May 2022	Licence extension to 2 December 2022 and introduction of supplementary reporting
309726	Genea Limited	31 May 2022	Licence extension to 2 December 2022 and introduction of supplementary reporting

Appendix C: 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 D: 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, 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.
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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