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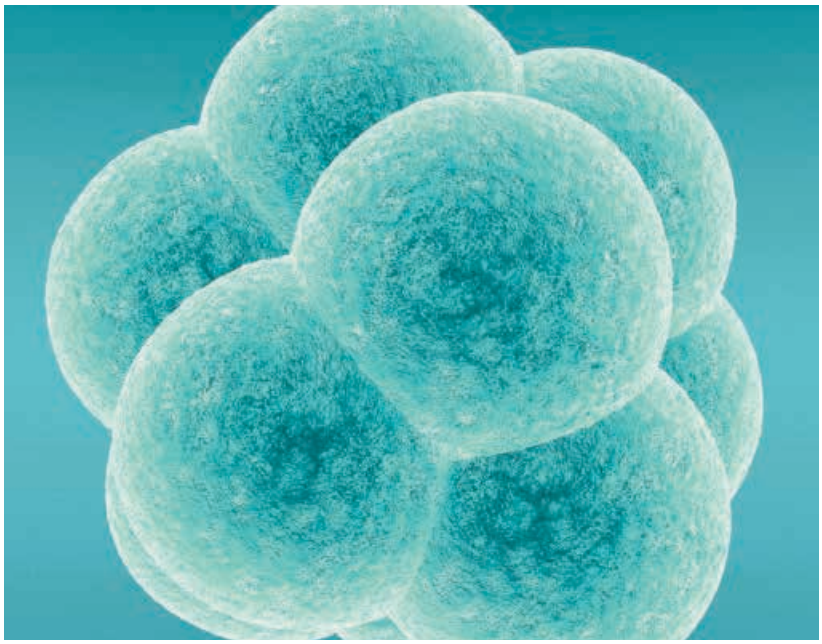
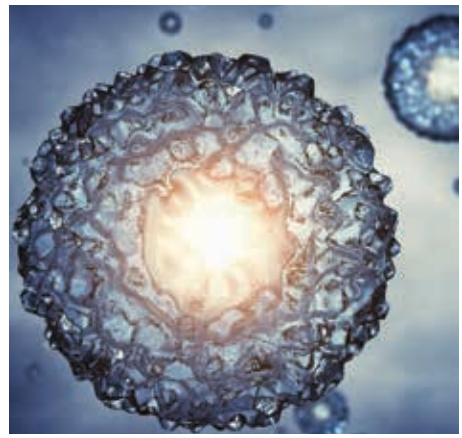
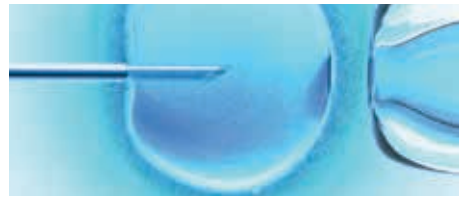




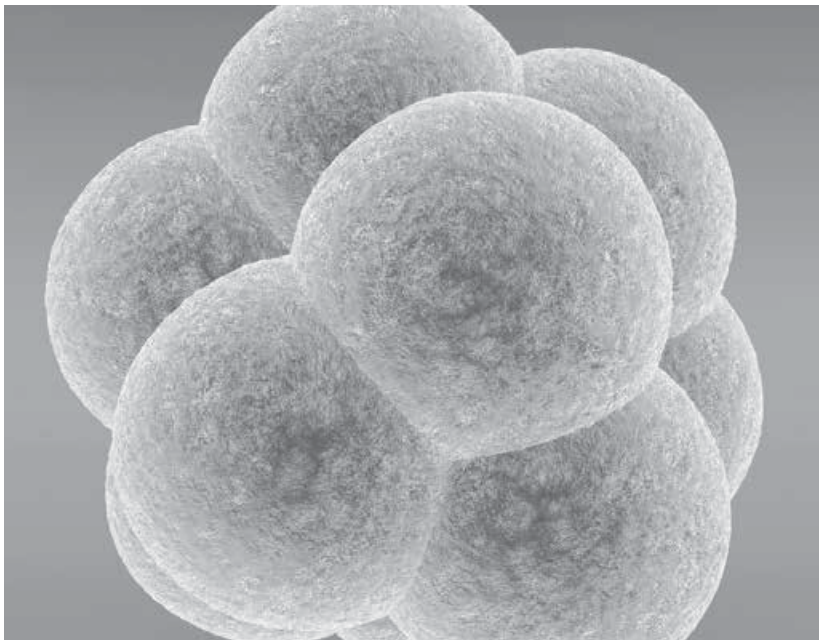


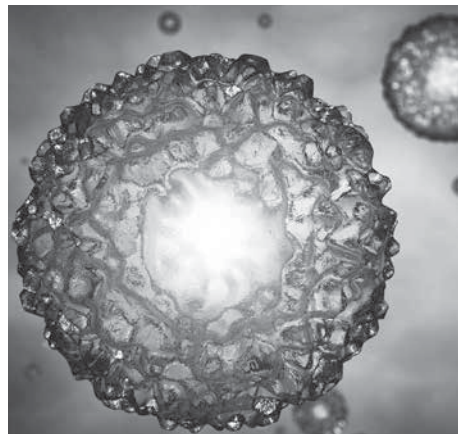
NHMRC Embryo Research Licensing Committee

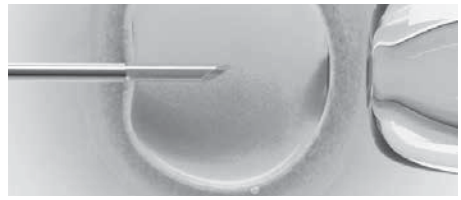
Report to the Parliament of Australia

For the period 1 September 2015 to 29 February 2016

WORKING TO BUILD A HEALTHY AUSTRALIA







NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia

For the period 1 September 2015 to 29 February 2016

WORKING TO BUILD A HEALTHY AUSTRALIA

Publication Details

Publication title:	NHMRC Embryo Research Licensing Committee: Report to the Parliament of Australia for the period 1 September 2015 to 29 February 2016
Published:	June 2016
Publisher:	National Health and Medical Research Council
NHMRC Publication reference:	HC48
Online version:	www.nhmrc.gov.au/guidelines/publications/hc48
ISBN Print:	978-1-925129-64-9
ISBN Online:	978-1-925129-65-6
Suggested citation:	National Health and Medical Research Council (2016) NHMRC Embryo Research Licensing Committee: Report to the Parliament of Australia for the period 1 September 2015 to 29 February 2016. Canberra: National Health and Medical Research Council

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The Hon Sussan Ley MP
Minister for Health
Parliament House
Canberra ACT 2600

Dear Minister Ley

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

This report is for the period 1 September 2015 to 29 February 2016 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 once during this reporting period, and has considered a number of applications seeking to vary previously issued licences for the use of excess assisted reproductive technology embryos and human eggs. In total nineteen licences have been issued under the Act, of which seven were current at 29 February 2016.

Yours sincerely

Professor Constantine (Con) Michael AO
Chairperson
NHMRC Embryo Research Licensing Committee
May 2016

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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 utilisation 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 the 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 C** to this report.

Reporting to Parliament

Section 19(3) of the RIHE Act requires the NHMRC Licensing Committee to table six-monthly 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 twenty-seventh Parliamentary Report of the NHMRC Licensing Committee, which covers the period 1 September 2015 to 29 February 2016.

Further information

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

The Director, Strategic Projects and Support
Evidence, Advice and Governance
NHMRC
GPO Box 1421
CANBERRA ACT 2601
Telephone: 02 6217 9000
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) which was passed by Federal Parliament in December 2002.

NHMRC Licensing Committee appointments for the 2015-2018 NHMRC triennium commenced on 13 August 2015. The current NHMRC Licensing Committee was appointed by the Minister for Health following consultation with relevant State and Territory Ministers and bodies prescribed in the regulations under the RIHE Act.

Members are appointed on a part-time basis for a period not exceeding three years, as specified in the instrument of appointment, and are eligible for reappointment. The nine-member NHMRC Licensing Committee is responsible for making statutory decisions as outlined in the RIHE Act.

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 23 November 2015.

Consideration of licence applications

No licence applications were received during the reporting period.

New licences issued

No licences were issued during the reporting period.

Variations to existing licences

The RIHE Act empowers the NHMRC Licensing Committee to vary a licence. Variations to licences may either be requested by the licence holder or initiated by the 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 eleven variations to licences.

These variations were initiated by licence holders as follows:

- one variation involved alterations to the consent process and documents
- ten variations involved changes to the lists of persons authorised to supervise or conduct the licensed activities.

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

Expiry of licences

Three licences expired during the reporting period. Licences 309712, 309713 and 309714 which had been issued to Genea Limited expired on 16 December 2015.

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 outcomes are provided here as received from the current licence holders.

Current licences

Licence number	**309702B**
Licence holder	Genea Limited
Licence title	Development of methods for pre-implantation 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, a total of thirty (30) 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 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	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 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 blastocyst stage embryos. After several protocol optimisations and development of consumables, the instrument and consumables are now in its final version and manufacturing is taking place. The instrument and media have now been accepted as CE marked products and are commercially distributed. The Gavi system now has approved protocols for freezing of blastocyst stage and cleavage stage embryos. Further optimisations for the freezing of oocytes are continuing.

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	No embryo research activity undertaken under this licence during this reporting period. The current version of Gems IVF medium suite, previously developed by Genea under this licence, is registered, CE marked and prepared for international distribution. Work on development of the next generation IVF media suite under this licence is planned for future reporting periods.

Licence number	309722
Licence holder	Monash IVF Pty Ltd
Licence title	Optimising embryo-endometrial interactions to improve pregnancy success during IVF
Progress of licensed activity to date	During this reporting period we did not thaw excess ART embryos. We have been analysing the data obtained so far on the interactions between trophectoderm and endometrial cells. The consenting process for donation of excess ART embryos to this licensed research continues with many patients keen to donate their excess ART embryos to this research project.

Licence number	**309723**
Licence holder	Melbourne IVF Pty Ltd
Licence title	Use of excess ART embryos for blastocyst-stage biopsy training
Progress of licensed activity to date	No activity to date

Expired Licences

Licence numbers	**309712, 309713, 309714**
Licence holder	Genea Limited
Licence title	309712: Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from human cumulus cells into clinically unusable human eggs 309713: Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs 309714: Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from previously established human embryonic stem cell lines into clinically unusable human eggs
Progress of licensed activity to date	No reproducible method for SCNT using clinically unsuitable eggs for the efficient epigenetic reprogramming of human cells to the blastocyst stage has been established during the lifetime of the projects. A total of 509 clinically unsuitable eggs have been entered into the SCNT projects. While several SCNT constructs developed to the 8-cell stage, unfortunately no further development was observed. Four constructs were plated for attempted derivation of an SCNT stem cell line, but no outgrowth occurred. Various improvements were tried. These included methods for *in vitro* maturation of immature eggs, different nuclear transfer techniques, various agents to support reprogramming and stem cell derivation. It was determined that the low quality of eggs deemed clinically unsuitable by clinical staff was ultimately the lead reason why the project could not be successful.

Licensed use of excess ART embryos

The following table shows the use of excess ART embryos under licence, as at 29 February 2016.

Current licences

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 29 February 2016	Embryos used during the reporting period
309702B	Genea Limited	Development of methods for pre-implantation genetic and metabolic evaluation of human embryos	220	50 (plus 8 embryos first used in 309701 and then transferred to 309702B)	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)	33
309710	Genea Limited	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known genetic 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	0	0
309722	Monash IVF Pty Ltd	Optimising embryo-endometrial interactions to improve pregnancy success during IVF	200	22	0
309723	Melbourne IVF Pty Ltd	Use of excess ART embryos for blastocyst-stage biopsy training	200	0	0
Total for current licences			**2405**	**884**	**33**

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 29 February 2016. "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 29 February 2016	Eggs used during the reporting period	'Other embryos' authorised to be created under licence	'Other embryos' created in licensed activity up to 29 February 2016	'Other embryos' created during the reporting period
309718	Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	1000	368	84	0	0	0
Total			**1000**	**368**	**84**	**0**	**0**	**0**

Expired licences

Licence number	Licence holder	Licence title	Eggs authorised to be used under licence	Eggs used in licensed activity up to 29 February 2016	Eggs used during the reporting period	'Other embryos' authorised to be created under licence	'Other embryos' created in licensed activity up to 29 February 2016	'Other embryos' created during the reporting period
309712	Genea Limited	Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from human cumulus cells into clinically unusable human eggs	2400	165	0	360	14*	0
309713	Genea Limited	Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs	2400	77	0	360	4*	0
309714	Genea Limited	Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from previously established human embryonic stem cell lines into clinically unusable human eggs	2400	267	0	360	23*	0
Total			**7200**	**509**	**0**	**1080**	**41**	**0**

* Of the human SCNT embryos that have so far been created under these licences, only one has developed to the compacted morula stage.

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 Monitoring and Compliance Framework can be found on the NHMRC website at www.nhmrc.gov.au.

Monitoring activities

During the reporting period, NHMRC inspectors conducted two inspections to assess compliance with licence conditions.

Licence Holder	Licence Number	Inspection Type	Inspection Date
Monash IVF Ltd	309722	Monitoring	19 November 2015
Genea Ltd	309712, 309713, 309714	Final	3 December 2015

Outcomes of monitoring activities conducted

Monitoring Activity	**Monitoring Inspection**
Licence Number	**309722**
Licence Holder	**Monash IVF Pty Ltd**
Monitoring Activity Date	**19 November 2015**
Licence Title	**Optimising embryo-endometrial interactions to improve pregnancy success during IVF**
Background	• Licence 309722 was issued on 11 December 2013. • This was the first inspection of Monash IVF conducted in relation to Licence 309722.
Activities Conducted During Inspection	• Reviewed licensed activity 309722. • Inspected and examined documents and records to confirm the integrity of Monash IVF's record keeping systems relevant to the licensed use of excess ART embryos in Licence 309722. • Tracked nine embryos used under Licence 309722 from the responsible persons to the outcomes of the licensed use. • Provided guidance to ensure continued compliance with licence conditions and legislation. • Obtained information on the licensed activities to keep the NHMRC Licensing Committee updated on the progress of the licence.
Findings Related to Licence Conditions	• The inspectors were satisfied with the licence holder's processes. • The licence holder provided all the information requested by the NHMRC inspectors.
Findings related to compliance with *Research Involving Human Embryos Act 2002*	• No contraventions of the *Research Involving Human Embryos Act 2002* were found.
Compliance Status	**Compliant**

Monitoring Activity	**Final Inspection**
Licence Number	**309712, 309713, 309714**
Licence Holder	**Genea Ltd**
Monitoring Activity Date	**3 December 2015**

Monitoring Activity	Final Inspection
Licence Title	**309712: Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from human cumulus cells into clinically unusable human eggs** **309713: Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs** **309714: Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from previously established human embryonic stem cell lines into clinically unusable human eggs**
Background	Licences 309712, 309713 and 309714 were issued on 16 September 2008. This was the fifth inspection of Genea Ltd conducted in relation to Licences 309712, 309713 and 309714. The outcomes of the previous inspections were reported in the 13th, 15th, 17th and 20th NHMRC Embryo Research Licensing Committee Reports to Parliament.
Activities Conducted During Inspection	Reviewed licensed activities. Examined documents and records to confirm the integrity of Genea's record keeping systems relevant to the licensed use of clinically unusable eggs and other cells in Licences 309712, 309713 and 309714. Tracked eight clinically unusable eggs used under the licences from the responsible persons to the outcomes of the licensed use. Obtained information on the outcomes of the licensed activities. Provided advice to the licence holder about their preparation to cease the licensed activity Assessed the licence holder's arrangements for complying with licence conditions related to the conclusion of the licensed activity.
Findings Related to Licence Conditions	The NHMRC inspectors were satisfied with the licence holder's processes. The licence holder provided all the information requested by the NHMRC inspectors. The licence holder was aware of all the implications associated with the expiry of the licence. In accordance with licence conditions and consent provided by responsible persons, arrangements were made to discard any eggs and cells that were not used in the authorised activities. The authorised activity occurred only at the authorised site and was performed by persons authorised on the licences. The licence holder provided the final reports required by the licence conditions before the licences expired on 16 December 2015.
Findings related to compliance with *Research Involving Human Embryos Act 2002*	No contraventions of the *Research Involving Human Embryos Act 2002* found.
Compliance Status	**Compliant**

Communication and awareness

The NHMRC Licensing Committee has published an information kit that can be accessed on the NHMRC 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: Current membership of the NHMRC Licensing Committee

Members of the NHMRC Licensing Committee for the 2015-2018 triennium are:

Professor Constantine (Con) Michael AO, Western Australia (Chairperson)
A person with expertise in the regulation of assisted reproductive technology

Professor Dianne Nicol, Tasmania
A member of the Australian Health Ethics Committee (AHEC)

Professor Sheryl de Lacey, South Australia
A person with expertise in research ethics

Professor Martin Pera, Victoria
A person with expertise in a relevant area of research

Dr Anne Clark, New South Wales
A person with expertise in assisted reproductive technology

Associate Professor Bernadette Richards, South Australia
A person with expertise in a relevant area of law

Mr Robert Pask, Victoria
A person with expertise in consumer health issues relating to disability and disease

Mr Michael Condon, Queensland
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, the NHMRC Licensing Committee approved the following variations to existing licences:

Licence No.	Organisation	Date of variation	Brief description of variation
309702B	Genea Ltd	25 November 2015	New Principal Supervisors
309718			
309703	Genea Ltd	25 November 2015	Removal of authorised persons
309710			
309718			
309718	Genea Ltd	25 November 2015	Variation to process for obtaining proper consent
309722	Monash IVF Pty Ltd	25 November 2015	Departure of Principal Supervisor Addition of Principal Supervisor
309723	Melbourne IVF Pty Ltd	25 November 2015	Addition of alternate Principal Supervisor
309723	Melbourne IVF Pty Ltd	25 November 2015	Departure of authorised persons
309723	Melbourne IVF Pty Ltd	25 November 2015	Addition of authorised persons
309719	Genea Ltd	18 January 2016	New Principal Supervisor Variation to authorised persons

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. At the 13 April 2007 Council of Australian Governments (COAG) meeting, all jurisdictions (except the Northern Territory) restated their commitment to introduce nationally consistent legislation.

At the end of the reporting period, Victoria, New South Wales, Tasmania, Queensland, the Australian Capital Territory and South Australia had all passed amending complementary legislation.

Victoria, Queensland, Tasmania, South Australia and the Australian Capital Territory have had their legislation declared as 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

Prohibition of Human Cloning for Reproduction Act 2008

New South Wales

Human Cloning for Reproduction and Other Prohibited Practices Act 2003

Research Involving Human Embryos (New South Wales) Act 2003

Tasmania

Human Embryonic Research Regulation Act 2003

Human Cloning for Reproduction and Other Prohibited Practices Act 2003

Queensland

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

South Australia

Prohibition of Human Cloning for Reproduction Act 2003
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)
Allegation	An assertion by a third party, other than the licence holder, of a breach against the legislation
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
COAG	The Council of Australian Governments is the peak intergovernmental forum in Australia. The members of COAG are 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
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)

Term	Description
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
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
Parthenogenetic	A process in which an unfertilised egg can be induced to develop like an embryo

Term	Description
Proper Consent	Consent obtained in accordance with the *Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research 2007*, 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
SCNT Construct	An entity created by the process of SCNT, which may or may not divide to become an "other embryo"

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