



NHMRC Embryo Research Licensing Committee
Report to the Parliament of Australia

For the period 1 March 2016 to 31 August 2016

Publication Details

Publication title:	NHMRC Embryo Research Licensing Committee: Report to Parliament of Australia for the period 1 March 2016 to 31 August 2016
Published:	November 2016
Publisher:	National Health and Medical Research Council
NHMRC Publication reference:	HC49
Online version:	www.nhmrc.gov.au/guidelines-publications/hc49
ISBN Print:	978-1-925129-75-5
ISBN Online:	978-1-925129-76-2
Suggested citation:	National Health and Medical Research Council (2016) NHMRC Embryo Research Licensing Committee: Report to the Parliament of Australia for the period 1 March 2016 to 31 August 2016. Canberra: National Health and Medical Research Council

Copyright

© Commonwealth of Australia 2016



All material presented in this publication is provided under a Creative Commons Attribution 4.0 International licence (www.creativecommons.org.au), with the exception of the Commonwealth Coat of Arms, NHMRC logo and any content identified as being owned by third parties. The details of the relevant licence conditions are available on the Creative Commons website (www.creativecommons.org.au), as is the full legal code for the CC BY 4.0 International licence.

Attribution

Creative Commons Attribution 4.0 International Licence is a standard form licence agreement that allows you to copy, distribute, transmit and adapt this publication provided that you attribute the work. The NHMRC's preference is that you attribute this publication (and any material sourced from it) using the following wording: Source: National Health and Medical Research Council.

Use of images

Unless otherwise stated, all images (including background images, icons and illustrations) are copyrighted by their original owners.

Contact us

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

E: nhmrc.publications@nhmrc.gov.au

P: (02) 6217 9000



Australian Government

National Health and Medical Research Council

GPO Box 1421 | Canberra ACT 2601
16 Marcus Clarke Street, Canberra City ACT 2600
T. 13 000 NHMRC (13 000 64672) or +61 2 6217 9000
F. +61 2 6217 9100
E. nhmrc@nhmrc.gov.au
www.nhmrc.gov.au

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-eighth 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 March 2016 to 31 August 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 twice 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 31 August 2016.

Yours sincerely

A handwritten signature in black ink that reads "Con. Michael".

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

Contents

Introduction	1
Legislative framework	1
Reporting to Parliament	1
Further information	2
Membership of the NHMRC Licensing Committee	3
Functions	3
Operation of the NHMRC Licensing Committee	4
Committee meetings	4
Consideration of licence applications	4
New licences issued	4
Variations to existing licences	5
Progress of licensed activities	6
Licence holder reports	6
Licensed use of excess ART embryos	9
Licensed use of human eggs or creation of other embryos	10
Monitoring compliance with the legislation	11
Monitoring activities	11
Outcomes of monitoring activities conducted	12
Communication and awareness	17
Information exchange visits	17
Appendix A: Current membership of the NHMRC Licensing Committee	18
Appendix B: Variations to licences	19
Appendix C: Corresponding State and Territory legislation	20
Appendix D: Glossary of Common Terms	21

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-eighth Parliamentary Report of the NHMRC Licensing Committee, which covers the period 1 March 2016 to 31 August 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.

During the reporting period, the member of Licensing Committee with expertise in consumer issues relating to assisted reproductive technology notified NHMRC of his intention to resign. A replacement member will be appointed by the Minister for Health following consultation with the relevant State and Territory Ministers and prescribed bodies, in accordance with 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 3 March 2016 and 2 June 2016.

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 33 variations to licences.

These variations were initiated by licence holders as follows:

- one variation related to the extension of a licence
- two variations related to details of the authorised activity
- one variation related to details of records required to be maintained in relation to the authorised activity
- five variations involved changes to the consent process
- two variations involved the addition of a training component and two variations changed details of a training component added previously
- three variations involved the addition of an authorised site
- seventeen variations involved changes to the lists of persons authorised to supervise and/or conduct the licensed activities.

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 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	<p>Under this licence, a total of thirty (30) cell lines have been derived, four of which are karyotypically abnormal.</p> <p>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.</p> <p>Cell lines are available to researchers worldwide for basic disease research and drug development projects. Various distribution services aid in this process.</p>

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 their final version and manufacturing is taking place. The instrument and media are CE marked products and are commercially distributed. The Gavi system now has approved protocols for freezing of blastocyst stage, zygotes and cleavage stage embryos. Further optimisations for the different developmental stages may be required depending on market feedback.

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 version of Gems IVF medium suite, previously developed by Genea under this licence, is registered, CE marked and prepared for international distribution. Further research is in progress to continually improve the current Gems IVF medium suite and where possible, increase the available product range. To that end, additional human research embryos are likely to be used to assist with development of the new compound for overlaying culture media in the next reporting period and subsequent to that, to develop the next generation of media solutions contained within the Gems IVF medium suite.

PROGRESS OF LICENSED ACTIVITIES

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 thawed excess ART embryos. We have set up the methods required to determine interactions between human 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	Licence Number 309723 involves the use of excess ART embryos to train scientists in the technique of embryo biopsy at the blastocyst stage of development. This technique involves removal of a small piece of tissue (trophectoderm) from the embryo and the processing of this tissue in a way that allows it to be subjected to genetic testing. Activities under this licence have resulted in three scientists demonstrating proficiency in this technique to a level required for clinical application.

Licensed use of excess ART embryos

The following table shows the use of excess ART embryos under licence, as at 31 August 2016.

Current licences

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 31 August 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)	0
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	38	38
309722	Monash IVF Pty Ltd	Optimising embryo-endometrial interactions to improve pregnancy success during IVF	200	60	38
309723	Melbourne IVF Pty Ltd	Use of excess ART embryos for blastocyst-stage biopsy training	150	100	100
Total for current licences			2355	1060	176

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 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 31 August 2016	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	39
Total			1000	407	39

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 five inspections to assess compliance with licence conditions.

Licence Holder	Licence Number	Inspection Type	Inspection Date
Genea Ltd	309703	Monitoring	19 May 2016
Genea Ltd	309710	Monitoring	19 May 2016
Genea Ltd	309718	Monitoring	19 May 2016
Genea Ltd	Not applicable	Site	19 May 2016
Melbourne IVF Pty Ltd	309723	Monitoring	26 May 2016

Outcomes of monitoring activities conducted

Monitoring Activity	Monitoring Inspection
Licence Number	309703
Licence Holder	Genea Ltd
Monitoring Activity Date	19 May 2016
Licence Title	Development of Human Embryonic Stem (ES) Cells
Background	<ul style="list-style-type: none"> • Licence 309703 was issued on 16 April 2004. • This is the tenth inspection of Genea Ltd conducted in relation to Licence 309703. The outcomes of the previous inspections have been reported in the 4th, 6th, 8th, 9th, 11th, 15th, 19th and 25th NHMRC Embryo Research Licensing Committee Reports to Parliament.
Activities Conducted During Inspection	<ul style="list-style-type: none"> • Reviewed licensed activity 309703. • Inspected and examined documents and records to confirm the integrity of Genea's record keeping systems relevant to the licensed use of excess ART embryos in Licence 309703. • Tracked four excess ART embryos used under Licence 309703 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	<ul style="list-style-type: none"> • 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 <i>Research Involving Human Embryos Act 2002</i>	<ul style="list-style-type: none"> • No contraventions of the <i>Research Involving Human Embryos Act 2002</i> were found.
Compliance Status	Compliant

Monitoring Activity	Monitoring Inspection
Licence Number	309710
Licence Holder	Genea Ltd
Monitoring Activity Dates	19 May 2016
Licence Title	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known serious monogenic conditions
Background	<ul style="list-style-type: none"> • Licence 309710 was issued on 7 May 2007. • This is the sixth inspection of Genea Ltd conducted in relation to Licence 309710. The outcomes of the previous inspections were reported in the 10th, 12th, 15th, 20th and 25th NHMRC Embryo Research Licensing Committee Reports to Parliament.
Activities Conducted During Inspection	<ul style="list-style-type: none"> • Reviewed licensed activity 309710. • Inspected and examined documents and records to confirm the integrity of Genea's record keeping systems relevant to the licensed use of excess ART embryos in Licence 309710. • Tracked three embryos used under Licence 309710 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	<ul style="list-style-type: none"> • 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 <i>Research Involving Human Embryos Act 2002</i>	<ul style="list-style-type: none"> • No contraventions of the <i>Research Involving Human Embryos Act 2002</i> were found.
Compliance Status	Compliant

Monitoring Activity	Monitoring Inspection
Licence Number	309718
Licence Holder	Genea Ltd
Monitoring Activity Dates	19 May 2016
Licence Title	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device
Background	<ul style="list-style-type: none"> • Licence 309718 was issued on 11 December 2011. • This is the third inspection of Genea Ltd conducted in relation to Licence 309718. The outcomes of the previous inspections were reported in the 19th and 25th NHMRC Embryo Research Licensing Committee Reports to Parliament.
Activities Conducted During Inspection	<ul style="list-style-type: none"> • Reviewed licensed activity 309718. • Inspected and examined documents and records to confirm the integrity of Genea's record keeping systems relevant to the licensed use of excess ART embryos and clinically unusable eggs in Licence 309718. • Tracked four excess ART embryos and eight clinically unusable eggs used under Licence 309718 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	<ul style="list-style-type: none"> • 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 <i>Research Involving Human Embryos Act 2002</i>	<ul style="list-style-type: none"> • No contraventions of the <i>Research Involving Human Embryos Act 2002</i> were found.
Compliance Status	Compliant

Monitoring Activity	Site Inspection
Licence Holder	Genea Ltd
Monitoring Activity Date	19 May 2016
Site	Genea Sydney North West
Background	<ul style="list-style-type: none"> • In February 2016 a fire in the building housing Genea's research laboratories resulted in damage to the laboratories. As repairs were likely to take several months, Genea applied for approval to transfer the activities authorised by Licences 309702B, 309718 and 309719 to alternative premises at Genea Sydney North West.
Activities Conducted During Inspection	<ul style="list-style-type: none"> • Viewed the research facilities at the alternative premises. • Confirmed the separation of clinical and research activities. • Confirmed ongoing access to documents and records relating to Genea's licensed activities. • Provided guidance to ensure continued compliance with licence conditions and legislation.
Findings Related to Sites	<ul style="list-style-type: none"> • The alternative site is appropriate for the activities. • The licence holder provided all the information requested by the NHMRC Inspectors.
Findings Related to compliance with <i>Research Involving Human Embryos Act 2002</i>	<ul style="list-style-type: none"> • No contraventions of the <i>Research Involving Human Embryos Act 2002</i> were found.
Compliance Status	Compliant

Monitoring Activity	Monitoring Inspection
Licence Number	309723
Licence Holder	Melbourne IVF Ltd
Monitoring Activity Date	26 May 2016
Licence Title	Use of excess ART embryos for blastocyst-stage biopsy training
Background	<ul style="list-style-type: none"> • Licence 309723 was issued on 19 December 2014. • This is the first inspection of Melbourne IVF conducted in relation to Licence 309723.
Activities Conducted During Inspection	<ul style="list-style-type: none"> • Reviewed licensed activity 309723. • Inspected and examined documents and records to confirm the integrity of Melbourne IVF's record keeping systems relevant to the licensed use of excess ART embryos in Licence 309723. • Tracked nine embryos used under Licence 309723 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 proposed activities under Licence 309723 to keep the NHMRC Licensing Committee updated on the progress of the licence.
Findings Related to Licence Conditions	<ul style="list-style-type: none"> • 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 <i>Research Involving Human Embryos Act 2002</i>	<ul style="list-style-type: none"> • No contraventions of the <i>Research Involving Human Embryos Act 2002</i> were 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

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	9 March 2016	Change to consent process
309703			
309710			
309718			
309719			
309703	Genea Ltd	9 March 2016	Addition of authorised person
309710			
309718			
309719			
309703	Genea Ltd	9 March 2016	Approval of additional techniques in training component
309710			
309718	Genea Ltd	9 March 2016	Approval of training component
309719			
309719	Genea Ltd	9 March 2016	Addition of Principal Supervisor
309702B	Genea Ltd	6 April 2016	Addition of site
309718			
309719			
309719	Genea Ltd	21 April 2016	Addition of authorised person
309710	Genea Ltd	27 April 2016	Extension of licence
309702B	Genea Ltd	6 June 2016	Departure of authorised persons
309703			
309710			
309718			
309703	Genea Ltd	6 June 2016	Departure of authorised trainee
309710			
309718			
309719			
309723	Melbourne IVF Pty Ltd	14 June 2016	Departure of Principal Supervisor
309723	Melbourne IVF Pty Ltd	14 June 2016	Departure of authorised person
309723	Melbourne IVF Pty Ltd	14 June 2016	Completion of prerequisite training
309723	Melbourne IVF Pty Ltd	14 June 2016	Changes to consent and authorised use spreadsheet
309723	Melbourne IVF Pty Ltd	14 June 2016	Change to definition of 'successful biopsy'
309722	Monash IVF Pty Ltd	24 June 2016	Variation to authorised activity

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.

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)
Application for a licence	Application form for a licence to conduct research activities permitted under section 20(1) of the <i>Research Involving Human Embryos Act 2002</i>
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 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 <i>Research Involving Human Embryos Act 2002</i> and the <i>Prohibition of Human Cloning for Reproduction Act 2002</i> are met
Embryonic Stem Cell	An undifferentiated cell that is a precursor to many different cell types, obtained from a preimplantation embryo, usually at the 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 <i>Research Involving Human Embryos Act 2002</i>
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

Term	Description
Inspection	An inspection of records, documents and premises to ensure compliance with licence conditions and the <i>Research Involving Human Embryos Act 2002</i> and the <i>Prohibition of Human Cloning for Reproduction Act 2002</i>
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	<i>In vitro</i> fertilisation
Monitoring	Activities conducted to assess the level of compliance with licence conditions, the <i>Research Involving Human Embryos Act 2002</i> and the <i>Prohibition of Human Cloning for Reproduction Act 2002</i>
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 <i>Research Involving Human Embryos Act 2002</i> 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
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 <i>Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research 2007</i> , 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”