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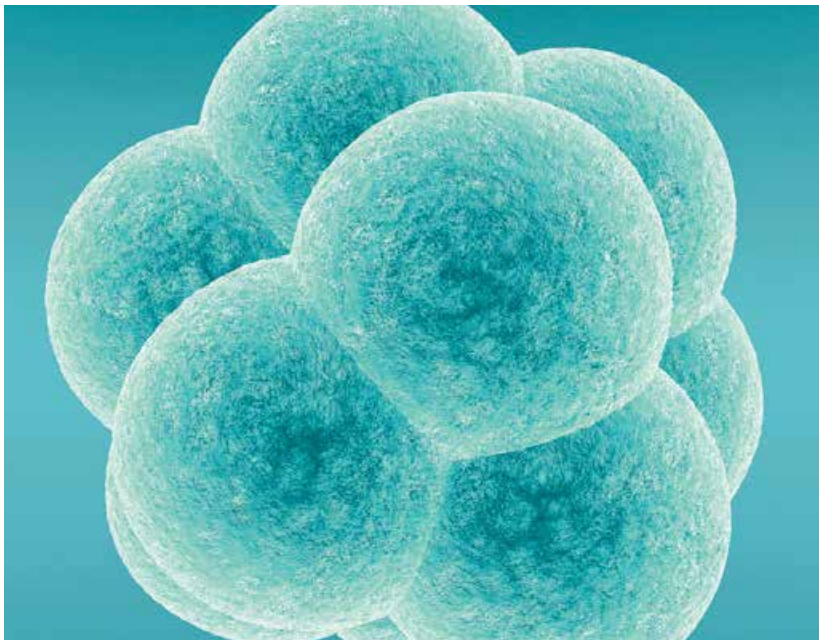
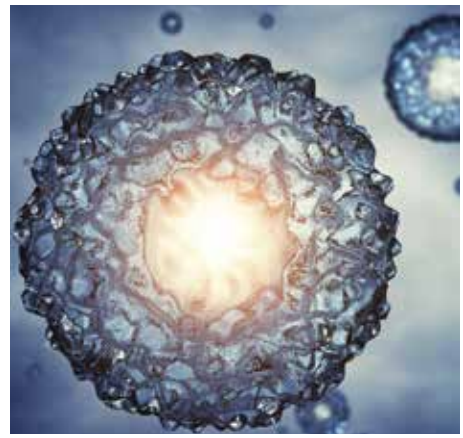
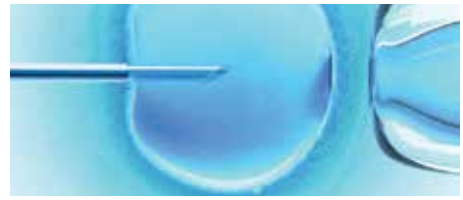




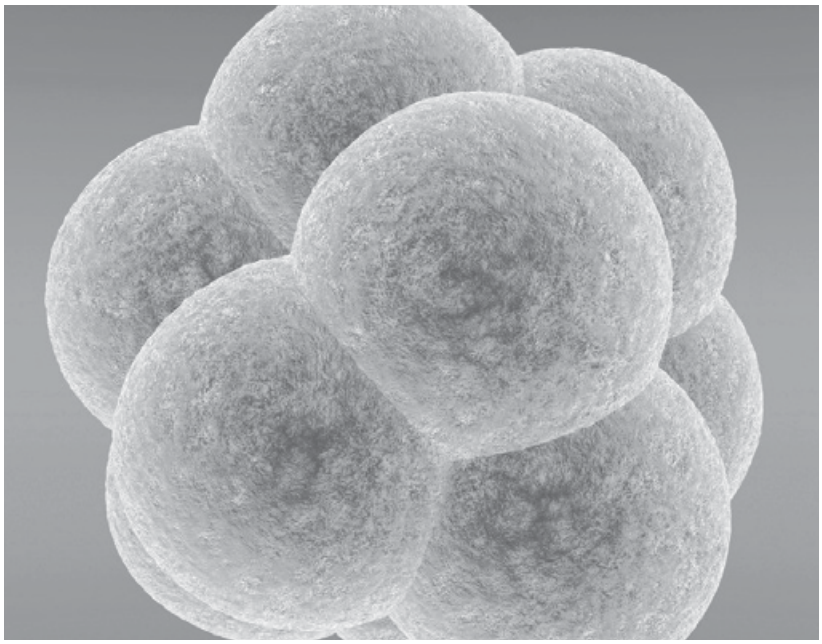


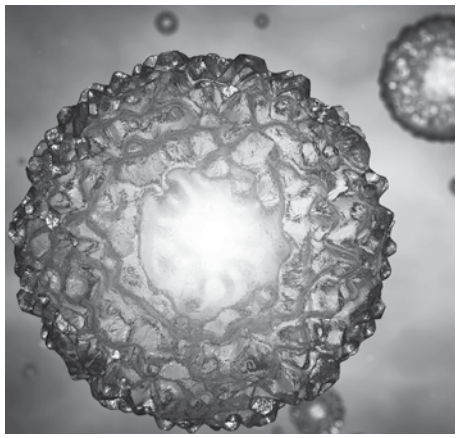
NHMRC Embryo Research Licensing Committee

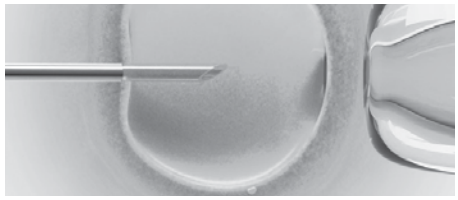
Report to the Parliament of Australia

For the period 1 March 2015 to 31 August 2015

WORKING TO BUILD A HEALTHY AUSTRALIA







NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia

For the period 1 March 2015 to 31 August 2015

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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-sixth 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 2015 to 31 August 2015 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 ten were current at 31 August 2015.

Yours sincerely

Professor Constantine (Con) Michael AO
Chairperson
NHMRC Embryo Research Licensing Committee
February 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-sixth Parliamentary Report of the NHMRC Licensing Committee, which covers the period 1 March 2015 to 31 August 2015.

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 2012-2015 NHMRC triennium ended on 30 June 2015.

NHMRC Licensing Committee appointments for the 2015-2018 NHMRC triennium commenced on 13 August 2015. However, the Chair and another member resigned while this report was in preparation and completion of the report was delayed until the appointment of replacement members was finalised. The Minister for Health appointed the NHMRC Licensing Committee 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; and
- 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 6 March 2015 and 12 June 2015. Both meetings were held by teleconference.

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:

- Two variations allow research staff to receive training in conjunction with their participation in the main licensed activity;
- One variation removed authorisation to use fresh excess ART embryos while retaining authorisation to use frozen excess ART embryos under the licence; and
- Eight 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

No licences expired during the reporting period.

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	Research performed under this licence allowed us to develop new approaches for the detection of chromosomally abnormal embryos prior to transfer.

Licence number	**309703**
Licence holder	Genea Limited
Licence title	Development of human embryonic (ES) cells
Progress of licensed activity to date	Under this licence, we have derived a total of twenty seven (27) cell lines, 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	**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 genetic 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	309712
Licence holder	Genea Limited
Licence title	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
Progress of licensed activity to date	No reproducible method for SCNT using clinically unsuitable eggs for the efficient epigenetic reprogramming of human cumulus cells to the blastocyst stage has been established to date. No activity has been performed during this reporting period.

Licence number	309713
Licence holder	Genea Limited
Licence title	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
Progress of licensed activity to date	No reproducible method for SCNT using clinically unsuitable eggs for the efficient epigenetic reprogramming of human fibroblast cells to the blastocyst stage has been established to date. No activity has been performed during this reporting period.

Licence number	309714
Licence holder	Genea Limited
Licence title	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 embryonic stem cells to the blastocyst stage has been established to date. No activity has been performed during this reporting period.

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 and test three prototypes, the Pre-production Unit and the Production Unit device (unit manufactured and sold to customers) of the vitrification instrument for the blastocyst stage freeze protocols. After several protocol optimisations being performed and development of consumables, the instrument and consumables are now in the final version and manufacturing is taking place. The instrument has recently been granted a CE Mark and the blastocyst protocol should be commercially available once a CE Mark for the media is granted. Genea's current focus under the licence is developing cleavage stage protocols. So far survival of recovered embryos is promising. However, more embryos are needed to validate the new software protocol in the next reporting period.

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. *Gems* IVF media suite, previously developed by Genea under this licence is currently registered 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

Licensed use of excess ART embryos

The following table shows the use of excess ART embryos under licence, as at 31 August 2015.

Current licences

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 31 August 2015	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)	228 (including 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	48
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	150	0	0
Total for current licences			**2355**	**863**	**48**

Licensed use of human eggs or creation of other embryos

The following table shows the use of human eggs or creation of other embryos under licence, as at 31 August 2015. "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 2015	Eggs used during the reporting period	'Other embryos' authorised to be created under licence	'Other embryos' created in licensed activity up to 31 August 2015	'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
309718	Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	1000	284	34	0	0	0
Total			**8200**	**793**	**34**	**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 *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002.* 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

NHMRC inspectors did not conduct any monitoring activities during the reporting period.

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

During the period of 1 March 2015 to 30 June 2015, the members of the NHMRC Licensing Committee were:

Professor Belinda Bennett, New South Wales (Chairperson)
A person with expertise in a relevant area of law

Ms Kay Oke, Victoria
A member of the Australian Health Ethics Committee (AHEC)

Associate Professor Lynn Gillam, Victoria
A person with expertise in research ethics

Professor Robert Norman AO, South Australia
A person with expertise in a relevant area of research

Dr Phillip Matson, Western Australia
A person with expertise in assisted reproductive technology

Ms Margaret Deane, Queensland
A person with expertise in consumer health issues relating to disability and disease

Ms Sandra Dill AM, New South Wales
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 Christopher O'Neill, New South Wales
A person with expertise in embryology

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 number	Organisation	Date of variation	Brief description of variation
309719	Genea Limited	11 March 2015	Departure of Alternate Principal Supervisor
309718	Genea Limited	26 March 2015	Departure of authorised person
309718	Genea Limited	26 March 2015	Addition of authorised person
309718	Genea Limited	14 April 2015	Addition of authorised persons
309710	Genea Limited	15 June 2015	Removal of option to use fresh excess ART embryos
309723	Melbourne IVF Pty Ltd	15 June 2015	Departure of authorised person
309718	Genea Limited	23 June 2015	Addition of authorised person
309703	Genea Limited	30 June 2015	Addition of authorised persons
309710			
309703	Genea Limited	30 June 2015	Allow training of research staff to be conducted in conjunction with main licensed activity
309710			

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

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)
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 *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
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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