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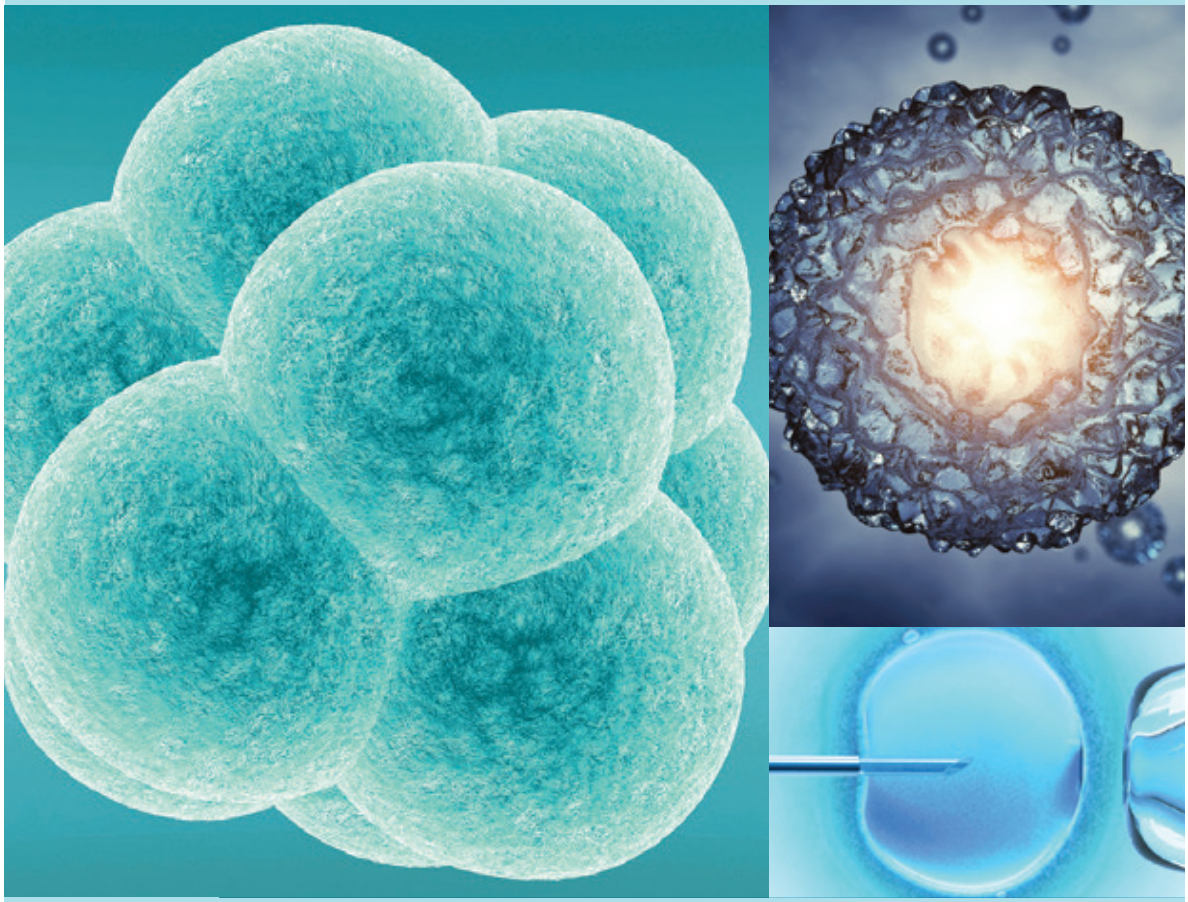
NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia

For the period 1 March to 31 August 2020



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Australian Government
National Health and Medical Research Council

NHMRC

The Hon Greg Hunt MP
Minister for Health
Parliament House
Canberra ACT 2600

Dear Minister Hunt

I am pleased to present to you the thirty-sixth 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 Act), reports on the operation of the Act and the licences issued under it.

This report is for the period 1 March to 31 August 2020 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 considered six applications seeking to vary previously issued licences for the use of excess assisted reproductive technology embryos and human eggs. In total 22 licences have been issued under the Act since the legislation commenced, of which eight were current at 31 August 2020.

Yours sincerely

Professor Dianne Nicol
Chairperson
NHMRC Embryo Research Licensing Committee
November 2020

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Table of 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 4

Licences suspended 4

Expiry of licences 4

Progress of licensed activities 5

Licence holder reports 5

Licensed use of excess ART embryos 8

Licensed use of human eggs or creation of other embryos 10

Monitoring compliance with the legislation 11

Monitoring activities 11

Communication and awareness 12

Information exchange visits 12

Appendix A: Membership of the NHMRC Licensing Committee 13

Appendix B: Variations to licences 14

Appendix C: Corresponding state and territory legislation 15

Appendix D: Glossary of Common Terms 16

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 thirty-sixth Parliamentary Report of the NHMRC Licensing Committee, which covers the period 1 March to 31 August 2020.

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, 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 2018–2021 NHMRC triennium commenced on 26 September 2018.

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 18 March 2020 and 28 July 2020.

Consideration of licence applications

The NHMRC Licensing Committee continued its assessment of an application received during the previous 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 issued under the Act. 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 six variations to licences, all initiated by licence holders, as follows:

- five variations involved a change to the list of persons authorised to conduct the licenced activity
- one variation involved a change of Principal Supervisor.

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

Licences suspended

One licence (309723) remained suspended for the duration of the reporting period. Further details are provided in this Report at the section titled 'Monitoring compliance with the legislation'.

Expiry of licences

Licence 309724, which had been issued to IVFAustralia Pty Ltd, expired on 21 April 2020.

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 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 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 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 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 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	**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 additional Embryos were donated for biopsy training. No Embryos were used for biopsy training. 5 Embryos were discarded due to expiry of VARTA storage period (#211, 212, 213, 214, 215).

Licence number	**309725**
Licence holder	TasIVF Pty Ltd
Licence title	Use of excess ART embryos for blastocyst-stage embryo biopsy training
Progress of licensed activity to date	Training in embryo biopsy for one trainee. 23 embryos thawed, 13 biopsied, 13 successfully biopsied, 13 found DNA after cell loading. Training was completed notification sent on the 31/08/2020.

Licence number	**309726**
Licence holder	Genea Limited
Licence title	Use of excess ART embryos for training in an alternate biopsy method (day five hatch and biopsy)
Progress of licensed activity to date	Since the issue of the licence in June 2019 the consent process has been initiated. At this time licence activity has not commenced as we are awaiting on sufficient number of consents to be granted from patients to start training several trainees simultaneously.

Expired licences

Licence number	**309724**
Licence holder	IVFAustralia Pty Ltd
Licence title	Use of excess ART embryos for blastocyst-stage biopsy training
Progress of licensed activity to date	Under the terms of this licence the embryos were used to train staff to competently biopsy blastocysts to mimic PGT biopsy process. During the course of this licence one staff member was trained using embryos consented to this licence. While this method was successful, the licence required much staff attention and an alternative method was devised without the limitations that using human licenced embryos involves.

Licensed use of excess ART embryos

The following tables show the use of excess ART embryos under licence, as at 31 August 2020.

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 2020	Embryos used during the reporting period
309702B	Genea Limited	Development of methods for pre-implantation 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 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	58	0
Total for current licences			**2005**	**928**	**0**

Current training licences

Licence number	Licence holder	Licence title	Embryos per trainee authorised to be used under licence[1]	Number of active authorised trainees at 31 August 2020	Embryos used in licensed activity up to 31 August 2020 (total, all trainees)[2]	Embryos used during the reporting period (total, all trainees)
309723[3]	Melbourne IVF Pty Ltd	Use of excess ART embryos for blastocyst-stage biopsy training	67[4]	2	210	0
309725	TasIVF Pty Ltd	Use of excess ART embryos for blastocyst-stage embryo biopsy training	52	1	121	23
309726	Genea Limited	Use of excess ART embryos for training in an alternate biopsy method (day five hatch and biopsy)	25	17	0	0
Total for current licences					344	23

Expired training licences

Licence number	Licence holder	Licence title	Embryos per trainee authorised to be used under licence[5]	Number of active authorised trainees at 31 August 2020	Embryos used in licensed activity up to 31 August 2020 (total, all trainees)[6]	Embryos used during the reporting period (total, all trainees)
309724	IVF Australia Pty Ltd	Use of excess ART embryos for blastocyst-stage biopsy training	24	4	13	0

1 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.

2 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.

3 Licence 309723 was suspended on 18 December 2019 and remained suspended at the end of the reporting period. No activity is permitted under this licence while it is suspended.

4 From 19 December 2014 to 10 December 2018 Melbourne IVF was permitted to thaw 50 embryos for each authorised trainee. From 11 December 2018, Melbourne IVF is permitted to thaw 67 embryos for each authorised trainee.

5 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.

6 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.

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 2020. “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 2020	Eggs used during the reporting period
309718	Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	1000	407	0
Total			**1000**	**407**	**0**

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 https://www.nhmrc.gov.au/research-policy/embryo-research-licensing.

Monitoring activities

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

Three breaches of licence conditions were identified though desktop document reviews during the reporting period:

Late submission of reports

During the review of the licence holder reports for the period 1 March to 31 August 2020, a minor breach of a licence condition was identified in relation to three licences (309702B, 309703 and 309710) all held by the same company, in that the report required by condition 3001 was provided after the due date.

A review found that whilst a technical breach of the conditions of the three licences did occur, the breach did not meet the requirements for an offence under the RIHE Act. When alerted to the breach, the licence holder provided all information requested by the NHMRC Embryo Research Licensing Committee advising that the delay in report provision had been caused by pandemic-related business disruption.

Suspended Licence

Licence 309723 remained suspended for the duration of the reporting period. The Licence was suspended on 18 December 2019 as the NHMRC Licensing Committee believed, on reasonable grounds, that licence condition 2301 had been breached. No authorised activity may occur under the licence until the NHMRC Licensing Committee lifts the suspension.

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: Membership of the NHMRC Licensing Committee

Members of the NHMRC Licensing Committee for the 2018-2021 triennium are:

Professor Dianne Nicol, Tasmania (Chairperson)
A person with expertise in a relevant area of law

Associate Professor Bernadette Richards, South Australia
A member of the Australian Health Ethics Committee (AHEC)

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

Professor Justin St. John, 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

Ms Dianne Petrie OAM, New South Wales
A person with expertise in consumer issues relating to disability and disease

Ms Kay Oke OAM, 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 approved the following variations to existing licences:

Licence No.	Organisation	Date of variation	Brief description of variation
309702B	Genea Limited	10 August 2020	Removal of authorised person from list of authorised persons
309718	Genea Limited	10 August 2020	Departure of Principal Supervisor Approval of new Principal Supervisor
309719	Genea Limited	10 August 2020	Removal of authorised persons from list of authorised persons
309719	Genea Limited	10 August 2020	Addition of new authorised person
309725	TasIVF Pty Ltd	2 June 2020	Addition of authorised trainee to list of authorised persons
309726	Genea Limited	10 August 2020	Removal of authorised person from list of 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.

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 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.
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.
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.

Term	Description
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 *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.
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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