



**Australian Government**

**National Health and  
Medical Research Council**

N H M R C

# NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia

For the period 1 April 2009 to 31 August 2009

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Australian Government

National Health and  
Medical Research Council

N H M R C

The Hon. Mark Butler MP  
Parliamentary Secretary for Health  
Parliament House  
Canberra ACT 2600

Dear Parliamentary Secretary Butler

I am pleased to present to you the fourteenth biannual report from 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 subsection 19(3) of the Act.

This report is for the period 1 April 2009 to 31 August 2009 and describes the activities the NHMRC Licensing Committee has undertaken during this reporting period, including associated monitoring and compliance activities.

The NHMRC Licensing Committee has met once during this reporting period, and has considered a number of variations to existing licences. No new licence applications were received during the reporting period. In total thirteen licences have been issued under the Act, of which ten were current at 31 August 2009. All licence holders are subject to ongoing monitoring by NHMRC inspectors to ensure strict compliance with the Act.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Jock Findlay".

Professor Jock Findlay AO  
Chairperson  
NHMRC Embryo Research Licensing Committee  
December 2009



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# Introduction

## Legislative framework

The Commonwealth *Prohibition of Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002* 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 Research Involving Human Embryos Act 2002* 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 *Research Involving Human Embryos Act 2002* 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](http://www.nhmrc.gov.au).

The Australian Parliament passed amendments to the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002* in December 2006. The amendments permit the licensing of some practices previously prohibited, such as the use of embryos created specifically for research through somatic cell nuclear transfer. Information about the implementation of complementary State and Territory legislation is included at Appendix C to this report.

## Reporting to Parliament

Subsection 19(3) of the *Research Involving Human Embryos Act 2002* 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 *Research Involving Human Embryos Act 2002* and about licences issued under this Act.

This is the fourteenth Parliamentary Report of the NHMRC Licensing Committee, which covers the period 1 April 2009 to 31 August 2009. The fourteenth Report to Parliament is the first report following implementation of revised reporting periods for licence holders. Consequently, the licence information in this report covers the period 1 April 2009 to 31 August 2009. Future reports will cover the periods 1 September to 28 or 29 February and 1 March to 31 August.

## Further information

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

NHMRC  
Licensing Section  
Quality and Regulation Branch  
GPO Box 1421  
CANBERRA ACT 2601

Telephone: (02) 6217 9000  
Facsimile: (02) 6217 9175  
Website: [www.nhmrc.gov.au](http://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* which was passed by Federal Parliament in December 2002.

Licensing Committee appointments for the 2006-2009 NHMRC triennium ceased on 30 June 2009. The Licensing Committee is appointed by the Parliamentary Secretary for Health following consultation with relevant State and Territory Ministers and bodies prescribed in the regulations under the *Research Involving Human Embryos Act 2002*. 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 Committee is responsible for making statutory decisions as outlined in this Act.

## 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 *Research Involving Human Embryos Act 2002* and the licences issued under this Act
- perform such other functions as are conferred on it by the *Research Involving Human Embryos Act 2002* or any other relevant law.

## Membership changes

The membership of the NHMRC Licensing Committee to 30 June 2009 is detailed at Appendix A.

# Operation of the NHMRC Licensing Committee

## Committee meetings

During the reporting period the NHMRC Licensing Committee met once on 27 May 2009.

## Consideration of licence applications

No new licence applications were received during the reporting period.

## New licences issued

No licences were issued during the reporting period.

## Variations to existing licences

The *Research Involving Human Embryos Act 2002* empowers the NHMRC Licensing Committee to vary a licence if the committee believes, on reasonable grounds, that it is necessary or desirable to do so. Variations to licences may either be requested by the licence holder or initiated by Committee members. Variations may range from those of an administrative nature (e.g. change to site address) to aspects of the authorised activities (e.g. number of embryos used).

During the reporting period, the NHMRC Licensing Committee approved 26 variations to licences.

Six of the variations were initiated by licence holders. One licence was varied to extend the duration of the licence. Five licence variations involved changes to the list of persons authorised to conduct licensed activities.

Twenty of the variations were initiated by the Licensing Committee. The Standard Conditions for all current licences were varied to introduce a change in reporting periods of 1 March to 31 August and 1 September to 28 (or 29) of February. The Special Conditions for all current licences were varied to implement a one off change to the reporting period of licence to 1 April 2009 to 31 August 2009 (five month period).

Further information about variations to 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 to date of their licensed activity are provided as received from current licence holders. Due to the change instituted to the reporting periods, discussed earlier, the reports provided below span a five month period.

### Current licences

Licence Number	<b>309701</b>
Licence Holder	Sydney IVF
Licence Title	Improvement in laboratory conditions for embryo culture.
Progress of Licensed Activity to Date	There has not been any activity during this reporting period for this licence.

Licence Number	<b>309702A</b>
Licence Holder	Sydney IVF
Licence Title	Effect of an additive on embryo culture: analysis of growth and epigenetic programming.
Progress of Licensed Activity to Date	The compound being assessed in this licence is currently undergoing evaluation in select clinics. The results from these evaluations will be used to determine if we need to alter the administration regimen (dose, timing, etc), do further testing or enter it into company wide evaluation trials.

Licence Number	<b>309702B</b>
Licence Holder	Sydney IVF
Licence Title	Development of methods for pre-implantation genetic and metabolic evaluation of human embryos.
Progress of Licensed Activity to Date	There has not been any activity during this reporting period for this licence.

<b>Licence Number</b>	<b>309703</b>
<b>Licence Holder</b>	Sydney IVF
<b>Licence Title</b>	Development of human embryonic stem (ES) cells.
<b>Progress of Licensed Activity to Date</b>	<p>Under this licence, we have derived a total of nineteen (19) cell lines with three (3) derived in the last reporting period. Currently we are working on the addition of a number of compounds to the derivation medium and different matrices to derive the cell lines in a Xeno-free (ie. animal product free) environment.</p> <p>Cell lines from this licence have been sent to a number of different collaborators locally and world-wide for use in basic research, disease modelling and therapeutic research.</p>

<b>Licence Number</b>	<b>309704</b>
<b>Licence Holder</b>	Melbourne IVF
<b>Licence Title</b>	Development of testing procedures for unbalanced chromosome errors in human embryos.
<b>Progress of Licensed Activity to Date</b>	There has been no activity during this reporting period for this licence.

<b>Licence Number</b>	<b>309709</b>
<b>Licence Holder</b>	Melbourne IVF
<b>Licence Title</b>	A collaborative project between Melbourne IVF Pty Ltd and Stem Cell Sciences Pty Ltd to derive human embryonic stem cell lines.
<b>Progress of Licensed Activity to Date</b>	There has been no activity during this reporting period for this licence. The licence holder has indicated they intend to surrender this licence in due course

<b>Licence Number</b>	<b>309710</b>
<b>Licence Holder</b>	Sydney IVF
<b>Licence Title</b>	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known genetic conditions.
<b>Progress of Licensed Activity to Date</b>	<p>Under this licence, seven affected stem cell lines (and one karyotypically abnormal outgrowth) have been derived. Three new cell lines have been derived during this reporting period (two with FSHD and one with Huntington's Disease), and those derived cell lines are currently undergoing characterisation.</p> <p>Our new lines in addition to those derived in previous reporting periods are available to researchers world wide for basic and advanced research projects. Our cell lines have been sent to iSTEM in France, CHDI (USA), Scripps Research Institute (USA) and APAF (Sydney), Novartis (USA), Singapore and Minnesota for use in collaborative studies into disease models.</p>

<b>Licence Number</b>	<b>309712</b>
<b>Licence Holder</b>	Sydney IVF
<b>Licence Title</b>	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.
<b>Progress of Licensed Activity to Date</b>	<p>April 2009 to September 2009 constituted a phase of the project during which the experimental protocols and consenting processes had to be optimised.</p> <p>At the end of this reporting period, 89 clinically unsuitable eggs have been entered into the 309712 project. Fifty-seven SCNT constructs have been created and so far development to the 8-cell stage has been observed. 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.</p>

<b>Licence Number</b>	<b>309713</b>
<b>Licence Holder</b>	Sydney IVF
<b>Licence Title</b>	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.
<b>Progress of Licensed Activity to Date</b>	<p>April 2009 to September 2009 constituted a phase of the project during which the experimental protocols and consenting processes had to be optimised.</p> <p>As skin cells are generally regarded as a somatic cell type that is more difficult to reprogram, skin cells will not be used as a source for somatic cell nuclei until the protocol for cumulus cells and human embryonic stem cells (hESCs) has advanced to a more conclusive level.</p> <p>Two skin cell samples from two unrelated female patients undergoing ART associated surgery were consented for, collected and cultured. To date no clinically unsuitable eggs have been entered into the 309713 project.</p> <p>No reproducible method for SCNT using clinically unsuitable eggs for the efficient epigenetic reprogramming of human skin cells to the blastocyst stage has been established to date.</p>

<b>Licence Number</b>	<b>309714</b>
<b>Licence Holder</b>	Sydney IVF
<b>Licence Title</b>	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.
<b>Progress of Licensed Activity to Date</b>	<p>April 2009 to September 2009 constituted a phase of the project during which the experimental protocols and consenting processes had to be optimised.</p> <p>To date 82 clinically unsuitable eggs have been entered into the 309714 project. Nineteen SCNT constructs have been created and so far development to the 8-cell stage has been observed.</p> <p>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.</p>

## Licensed use of excess ART embryos

The following table shows the use of excess ART embryos under licence, as at 31 August 2009.

Licence Number	Licence Holder	Licence Title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 31 August 2009	Embryos used during the reporting period
<b>Current Licences</b>					
309701	Sydney IVF	Improvement in laboratory conditions for embryo culture	670	73	0
309702A	Sydney IVF	Effect of an additive on embryo culture: analysis of growth and epigenetic programming	170	43	0
309702B	Sydney IVF	Development of methods for pre-implantation genetic and metabolic evaluation of human embryos	50 (plus another 170 transferred from 309701)	25	0
309703	Sydney IVF	Development of human embryonic stem (ES) cells	200 (plus up to 20 inner cell masses which may be transferred from 309702A or 309702B)	144	48
309704	Melbourne IVF	Development of testing procedures for unbalanced chromosome errors in human embryos	300	99	0
309709	Melbourne IVF	A collaborative project between Melbourne IVF Pty Ltd and Stem Cell Sciences Pty Ltd to derive human embryonic stem cell lines	200	97	0
309710	Sydney IVF	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known genetic conditions	100	59	14
<b>Total for current licences</b>			<b>1690</b>	<b>540</b>	<b>62</b>

## 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 2009. "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.

### Current Licences

Licence Number	309712	309713	309714	Total
Licence Holder	Sydney IVF	Sydney IVF	Sydney IVF	
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.	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.	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.	
Eggs authorised to be used under licence	2400	2400	2400	<b>7200</b>
Eggs used in licensed activity up to 31 August 2009	89	0	82	<b>171</b>
Eggs used during the reporting period	63	0	57	<b>120</b>
"Other embryos" authorised to be created under licence	360	360	360	<b>1080</b>
"Other embryos" created in licensed activity up to 31 August 2009	13*	0	6*	<b>19</b>
"Other embryos" created during the reporting period	7*	0	5*	<b>16</b>

\* Although human SCNT embryos have been created under this licence, none of them developed beyond the 8-cell 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* 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](http://www.nhmrc.gov.au).

## Monitoring activities

During the reporting period, NHMRC inspectors conducted inspections of three licences to ensure compliance with licence conditions.

Licence Holder Name	Licence Number	Inspection Type	Inspection Date
Sydney IVF	309701	Monitoring	21 May 2009
	309702a		
	309702b		

## Outcomes of monitoring activities conducted

<b>Monitoring Activity</b>	<b>Monitoring Inspection</b>
<b>Licence Numbers</b>	<b>309701, 309702A and 309702B</b>
<b>Licence Holder</b>	<b>Sydney IVF</b>
<b>Monitoring Activity Date</b>	<b>21 May 2009</b>
<b>Licence Titles</b>	<ul style="list-style-type: none"> <li>• 309701 'Improvement in laboratory conditions for embryo culture'</li> <li>• 309702A 'Effect of an additive on embryo culture: analysis of growth and epigenetic programming'</li> <li>• 309702B 'Development of methods for preimplantation genetic and metabolic evaluation of human embryos'.</li> </ul>
<b>Background</b>	<ul style="list-style-type: none"> <li>• On 16 April 2004 Sydney IVF was issued with Licences 309701, 309702A and 309702B.</li> <li>• This is the fourth inspection of Sydney IVF conducted in relation to Licences 309701 and 309702A. The outcomes of the previous 3 inspections have been reported in the 4th, 6th and 9th NHMRC Embryo Research Licensing Committee biannual reports to the Australian Parliament.</li> <li>• This is the fifth inspection of Sydney IVF conducted in relation to Licence 309702B. The outcomes of the previous four inspections have been reported in the 4th, 6th, 9th, and 11th, NHMRC Embryo Research Licensing Committee biannual reports to the Australian Parliament.</li> </ul>
<b>Activities Conducted During Inspection</b>	<ul style="list-style-type: none"> <li>• Reviewed licensed activity 309701, 309702A and 309702B.</li> <li>• Obtained information on the licensed activities to keep the NHMRC Licensing Committee updated on the progress of the Licences.</li> <li>• Inspected and examined documents and records to confirm the integrity of the Sydney IVF record keeping systems relevant to the licensed use of excess ART embryos in Licences 309701, 309702A and 309702B.</li> <li>• Tracked selected excess ART embryos used under Licence 309701, 309702A and 309702B from the responsible persons to the outcomes of the licensed use.</li> <li>• Provided guidance to ensure continued compliance with licence conditions and legislation.</li> <li>• Noted the full cooperation of Sydney IVF who provided all requested documentation and information.</li> </ul>
<b>Findings Related to Licence Conditions</b>	<ul style="list-style-type: none"> <li>• Sydney IVF was cooperative and provided all requested documents and information.</li> <li>• The inspectors were satisfied with the processes for meeting all conditions attached to the licences, including those relating to proper consent, tracking of excess ART embryos, record keeping and reporting to the NHMRC Embryo Research Licensing Committee.</li> </ul>

<i>Prohibition of Human Cloning for Reproduction Act 2002 Findings</i>	<ul style="list-style-type: none"> <li>• No breaches of the <i>Prohibition of Human Cloning for Reproduction Act 2002</i> were detected.</li> </ul>
<i>Research Involving Human Embryos Act 2002 Findings</i>	<ul style="list-style-type: none"> <li>• No breaches of the <i>Research Involving Human Embryos Act 2002</i> were detected.</li> </ul>
Compliance Status	<b>Compliant</b>

## Investigations

While routine compliance monitoring was undertaken during the reporting period (see above), no compliance issues arose that required further investigation.

## Communication and Awareness

The NHMRC has a communication strategy that includes ensuring information about the legislation is easily accessible.

A range of information concerning the operation of the *Research Involving Human Embryos Act 2002* can be accessed on the NHMRC website at:  
[www.nhmrc.gov.au](http://www.nhmrc.gov.au)

## Information exchange meetings

No information exchange meetings were conducted during this reporting period.

## Appendix A: Membership of the NHMRC Licensing Committee

During the period of 1 April 2009 to the 30 June 2009, the members of the NHMRC Licensing Committee were:

Professor John (Jock) Findlay AO, Victoria (Chairperson)

*A person with expertise in a relevant area of research*

Professor Peter Sainsbury, New South Wales

*A member of the Australian Health Ethics Committee (AHEC)*

Dr Peter McCullagh, New South Wales

*A person with expertise in research ethics*

Professor Geoffrey Driscoll, New South Wales

*A person with expertise in assisted reproductive technology*

Professor Donald Chalmers, Tasmania

*A person with expertise in a relevant area of law*

Dr Kay Pearce, Queensland

*A person with expertise in consumer health issues relating to disability and disease*

Dr Julia Nicholls OAM, South Australia

*A person with expertise in consumer issues relating to assisted reproductive technology*

Dr Helen Szoke, Victoria

*A person with expertise in the regulation of assisted reproductive technology*

Dr Stephen Junk, Western Australia

*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
309701	Sydney IVF	2 June 2009	Removal of authorised person from licence
309702A	Sydney IVF		
309702B	Sydney IVF		
309703	Sydney IVF		
309710	Sydney IVF		
309709	Melbourne IVF	3 June 2009	Extend the duration of the licence, until 11 June 2010
309701	Sydney IVF	27 July 2009	Change to Standard Condition 3001 to change reporting periods, from 1 April to 30 September to 1 March to 31 August, and from 1 October to 31 March to 1 September to 28 (or 29) February.
309702A	Sydney IVF		
309702B	Sydney IVF		
309703	Sydney IVF		
309704	Melbourne IVF		
309709	Melbourne IVF		
309710	Sydney IVF		
309712	Sydney IVF		
309713	Sydney IVF		
309714	Sydney IVF		
309701	Sydney IVF	27 July 2009	Variation of special conditions to implement the revised reporting period in the Standard Conditions, by including a reporting period of 1 April 2009 to 31 August 2009.  Addition of condition 9401 (licences 309702a and 309704), 9402 (licences 309701, 309702b), 9203 (licence 309703), 9405 (licence 309709), 9406 (licence 309710) and 9407 (licences 309712, 309713 and 309714).
309702A	Sydney IVF		
309702B	Sydney IVF		
309703	Sydney IVF		
309704	Melbourne IVF		
309709	Melbourne IVF		
309710	Sydney IVF		
309712	Sydney IVF		
309713	Sydney IVF		
309714	Sydney IVF		

## Appendix C: Corresponding state legislation

Following the passage of the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*, embryo research in Australia must comply with both Commonwealth and corresponding state/territory legislation. At the 13 April 2007 COAG meeting, all jurisdictions (except the Northern Territory) restated their commitment to introduce nationally consistent legislation.

Victoria, New South Wales, Tasmania, Queensland, the ACT and South Australia have all passed amending complementary legislation.

Victoria, Queensland, Tasmania and the ACT 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

*Infertility Treatment Amendment Act 2007*

### New South Wales

*Human Cloning and Other Prohibited Practices Amendment Act 2007*

### Tasmania

*Human Cloning and Other Prohibited Practices Amendment Bill 2007*

### Queensland

*Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007*

### South Australia

*Statutes Amendment (Prohibition of Human Cloning for Reproduction and Regulation of Research involving Human Embryos) Act 2009*

### ACT

*Human Cloning and Embryo Research Amendment Act 2008*

## Appendix D: Glossary

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 <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
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
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 8 of the <i>Research Involving Human Embryo Act 2002</i>
Gametes	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 <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
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	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





