

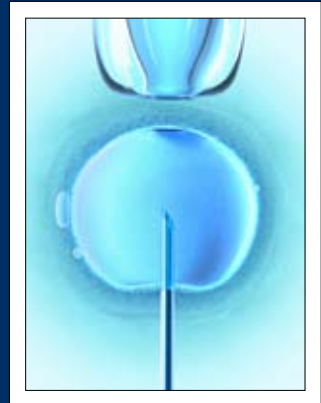
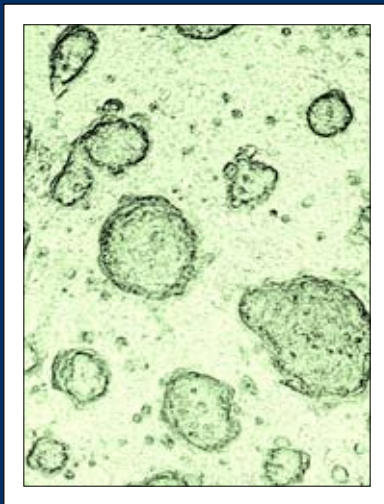
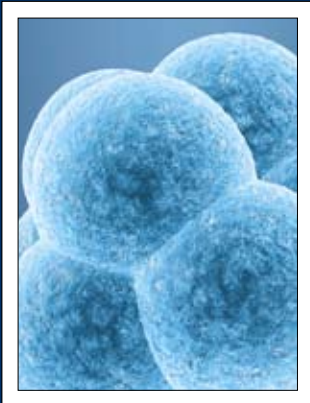


Australian Government

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 October 2008 to 31 March 2009



Australian Government

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Medical Research Council**

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Australian Government

National Health and
Medical Research Council

N H M R C

Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
Canberra ACT 2600

Dear Parliamentary Secretary,

I am pleased to present to you the thirteenth 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 October 2008 to 31 March 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 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. Two new licence applications were received during the reporting period and are presently being assessed by the NHMRC Licensing Committee. In total thirteen licences have been issued under the Act, of which ten were current at 31 March 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
June 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.

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 thirteenth Parliamentary Report of the NHMRC Licensing Committee, which covers the period 1 October 2008 to 31 March 2009.

Further information

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

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

Telephone: 02 6217 9000
Facsimile: 02 6217 9175
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* which was passed by Federal Parliament in December 2002.

Current appointments to the NHMRC Licensing Committee coincide with the 2006-2009 NHMRC triennium. 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

As noted in the twelfth report of the NHMRC Licensing Committee, the position for *a person with expertise in consumer issues relating to disability and disease* became vacant following the death of Associate Professor Christopher Newell in June 2008. Dr Kay Pearse was appointed to the position in March 2009 and will serve until the end of the triennium.

The current membership of the NHMRC Licensing Committee is detailed at Appendix A.

Operation of the NHMRC Licensing Committee

Committee meetings

During the reporting period the NHMRC Licensing Committee met on 3 December 2008 and 13 March 2009.

Consideration of licence applications

Two new licence applications were received during the reporting period. The NHMRC Licensing Committee is considering the applications in accordance with the *Research Involving Human Embryos Act 2002*.

New licences issued

No licences have been 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 24 variations to licences:

- Four of the variations were initiated by licence holders. All of these variations were to extend the duration of licences.
- Ten of the variations for all licences revised the Standard Conditions and were initiated by the NHMRC Licensing Committee.
- Ten of the variations were initiated by the NHMRC Licensing Committee and revised the Special Conditions.

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

Expiry of licences

Licence 309708 held by IVF Australia expired on 5 November 2008.

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.

Current licences

Licence Number	309701
Licence Holder	Sydney IVF
Licence Title	Improvement in laboratory conditions for embryo culture.
Progress of Licensed Activity to Date	The impact of the addition of the first compound tested under the licence to our embryo media suite continues to show a positive influence on the development of the embryo compared to the control media.

Licence Number	309702A
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 tested continues to provide a positive impact on the development of the embryos and does not have any negative impact on the epigenetics of the embryos tested compared to embryos grown in the current version of the culture media suite.

Licence Number	309702B
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.

Licence Number	309703
Licence Holder	Sydney IVF
Licence Title	Development of human embryonic (ES) cells.
Progress of Licensed Activity to Date	<p>To date 91 embryos and twelve (12) inner cell masses have been used for this project. We have produced a total of sixteen (16) cell lines with four (4) derived in the last reporting period. Currently we are working on the addition of a number of compounds to the derivation media to improve derivation rates.</p> <p>We have collaborations with Scripps Research Institute (La Jolla California) and APAF (Sydney) to provide in-depth molecular and protein analysis of these cell lines.</p>

Licence Number	309704
Licence Holder	Melbourne IVF
Licence Title	Development of testing procedures for unbalanced chromosome errors in human embryos.
Progress of Licensed Activity to Date	<p>Some individuals carry a balanced chromosome rearrangement where segments of their chromosomes have broken off and swapped position. This usually has little effect on the carrier except that their embryos are at high risk of having additional or missing chromosome segments. This causes miscarriage or birth of a child with a significant disability.</p> <p>Chromosome imbalance can be diagnosed in early embryos through preimplantation genetic diagnosis (PGD) using single cell fluorescent in situ hybridisation (FISH). Because the breakpoints can involve any location on any chromosome individualised FISH tests must be developed for almost every couple. This is achieved using blood cells initially but the ultimate test of whether the FISH strategy works effectively is to use cells from embryos.</p> <p>In this project we have used individual cells from human embryos to assist in the development of PGD FISH tests for 14 couples who carry chromosome rearrangements. These 14 couples have utilised the tests we have developed in their attempts to achieve a healthy pregnancy. No tests were performed during this reporting period.</p>

Licence Number	309709
Licence Holder	Melbourne IVF
Licence Title	A collaborative project between Melbourne IVF Pty Ltd and Stem Cell Sciences Pty Ltd to derive human embryonic stem cell lines.
Progress of Licensed Activity to Date	<p>The four 'MEL' human embryonic stem cell lines derived from work covered by this licence are being used nationally and internationally in fundamental research and commercial applications. MEL-1 and 2 are distributed through the UK Stem Cell Bank and Millipore, are part of two European Union funded programs (EU-Framework Program 7 and the International Stem Cell Initiative-II) seeking to better understand embryonic stem cell biology, and are also used by Stem Cell Sciences to generate a novel type of nerve stem cell for potential therapeutic and drug discovery applications. The lines are also used by two companies to develop embryonic stem cell specific antibodies, and novel growth media.</p>

Licence Number	309710
Licence Holder	Sydney IVF
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	Thus far we have derived 4 affected stem cell lines under this licence. Two new stem cell lines with cystic fibrosis have been derived in this reporting period which are being characterised. Our new lines in addition to our two lines affected with Huntington's disease and one karyotypically abnormal outgrowth with facioscapulohumeral muscular dystrophy will be available to researchers world wide for basic and advanced research projects. Our cell lines have been sent to iSTEM in France, CHDI, Scripps Research Institute (La Jolla, California) and APAF (Sydney) for collaborative studies.

Licence Number	309712
Licence Holder	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.
Progress of Licensed Activity to Date	October 2008 to March 2009 constituted a preparatory phase of the project during which the basis for a smooth experimental progression had to be established. To date 26 clinically unsuitable eggs have been entered into the 309712 project. Twenty-two SCNT constructs have been created and so far development to the 4-cell stage has been observed.

Licence Number	309713
Licence Holder	Sydney IVF
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	October 2008 to March 2009 constituted a preparatory phase of the project during which the basis for a smooth experimental progression had to be established. To date no clinically unsuitable eggs have been entered into the 309713 project.

Licence Number	309714
Licence Holder	Sydney IVF
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	<p>October 2008 to March 2009 constituted a preparatory phase of the project during which the basis for a smooth experimental progression had to be established.</p> <p>To date 25 clinically unsuitable eggs have been entered into the 309714 project. Two SCNT constructs have been created and so far development to the 8-cell stage has been observed.</p>

Expired Licences

Licence Number	309708
Licence Holder	IVF Australia
Licence Title	A collaborative project between IVF Australia and the Diabetes Transplant Unit, Prince of Wales Hospital, to derive human embryonic stem cell lines for the treatment of diabetes.
Progress of Licensed Activity to Date	<p>During the period of the licence a total of 50 embryos were thawed and cultured yielding 15 blastocyst stage embryos suitable to attempt isolation of cells to establish stem cell colonies. Two fully characterised stem cell lines, Endeavour 1 (END1) and Endeavour 2 (END2) were established. The development and characterisation of END1 has been published in the international scientific journal, <i>Stem Cells & Development</i>.</p>

Licensed use of excess ART embryos

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

Licence Number	Licence Holder	Licence Title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 31 March 2009
Current Licences				
309701	Sydney IVF	Improvement in laboratory conditions for embryo culture	670	73
309702A	Sydney IVF	Effect of an additive on embryo culture: analysis of growth and epigenetic programming	170	42
309702B	Sydney IVF	Development of methods for pre-implantation genetic and metabolic evaluation of human embryos	50 (plus another 170 transferred from 309701)	25
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)	96
309704	Melbourne IVF	Development of testing procedures for unbalanced chromosome errors in human embryos	300	99
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
309710	Sydney IVF	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known genetic conditions	100	45
Total for current licences			1690	477

Licence Number	Licence Holder	Licence Title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 31 March 2009
Expired Licence				
309708	IVF Australia	A collaborative project between IVF Australia and the Diabetes Transplant Unit, Prince of Wales Hospital, to derive human embryonic stem cell lines for the treatment of diabetes	100	50
Total for expired licence			100	50

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 March 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.

Licence Number	Licence Holder	Licence Title	Eggs authorised to be used under licence	Eggs used in licensed activity up to 31 March 2009	"Other embryos" authorised to be created under licence	"Other embryos" created in licensed activity up to 31 March 2009
Current Licences						
309712	Sydney IVF	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	26	360	6*
309713	Sydney IVF	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	0	360	0
309714	Sydney IVF	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	25	360	1*
	Total		7200	51	1080	7

* 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.

Monitoring activities

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

Licence Holder Name	Licence Number	Inspection Type	Inspection Date
IVF Australia	309708	Final*	28 October 2008
Sydney IVF	309712	Records audit	29 October 2008
	309713		
	309714		

* Licence 309708 expired on 5 November 2008. No further excess ART embryos will be used under this licence.

Outcomes of monitoring activities conducted

Monitoring Activity	Final Inspection
Licence Number	309708
Licence Holder	IVF Australia
Monitoring Activity Date	28 October 2008
Licence Title	A collaborative project between IVF Australia and the Diabetes Transplant Unit, Prince of Wales Hospital to derive Human Embryonic Stem Cell Lines for the treatment of Diabetes.
Background	<ul style="list-style-type: none"> On 5 November 2004 IVF Australia was issued with Licence 309708. This was the sixth inspection conducted in relation to Licence 309708. The outcomes of the previous five inspections were reported in the fifth, sixth, seventh, ninth and eleventh NHMRC Embryo Research Licensing Committee biannual reports to the Australian Parliament.
Activities Conducted During Inspection	<ul style="list-style-type: none"> Provided advice to the licence holder in their preparation to cease the licensed activity. Assessed the licence holder's arrangements for complying with licence conditions related to the conclusion of the licensed activity.
Findings Related to Licence Conditions	<ul style="list-style-type: none"> IVF Australia was cooperative and provided all documents and information requested. The licence holder was aware that the authorised activity must cease with the expiry of the licence. In accordance with licence conditions, arrangements will be made to manage any embryos that were not used in the authorised activities. The authorised activity occurred only at the authorised site and was performed by persons authorised by the licence. The authorised activity was conducted in accordance with the licence conditions.
<i>Prohibition of Human Cloning for Reproduction Act 2002 Findings</i>	<ul style="list-style-type: none"> No breaches of the <i>Prohibition of Human Cloning for Reproduction Act 2002</i> were detected.
<i>Research Involving Human Embryos Act 2002 Findings</i>	<ul style="list-style-type: none"> No breaches of the <i>Research Involving Human Embryos Act 2002</i> were detected.
Compliance Status	Compliant

Monitoring Activity	Records Audit Inspection
Licence Number	309712, 309713 and 309714
Licence Holder	Sydney IVF
Monitoring Activity Date	29 October 2008
Licence Titles	<p>309712 - Reproducible production of human embryonic stem cells lines from somatic cell nuclear transfer (SCNT) of nuclei from human cumulus cells into clinically unusable human eggs.</p> <p>309713 - Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs.</p> <p>309714 - Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from previously established human embryonic stem cell lines into clinically unusable human eggs.</p>
Background	<ul style="list-style-type: none"> On 16 September 2008, Sydney IVF was issued with Licences 309712, 309713 and 309714. This was the first inspection of Sydney IVF conducted in relation to Licences 309712, 309713 and 309714.
Activities Conducted During Inspection	<ul style="list-style-type: none"> Inspection and examination of documents and records to confirm the integrity of the Sydney IVF record keeping systems relevant to the licensed use of clinically unsuitable eggs and somatic cells in Licences 309712, 309713 and 309714. Provision of guidance to ensure continued compliance with licence conditions and legislation.
Findings Related to Licence Conditions	<ul style="list-style-type: none"> Sydney IVF was cooperative and provided all requested documents and information. The inspectors were satisfied with the processes for meeting all conditions attached to the licences, including those relating to proper consent, tracking of donated clinically unusable eggs and somatic cells, record keeping and reporting to the NHMRC Embryo Research Licensing Committee.
Prohibition of Human Cloning for Reproduction Act 2002 Findings	<ul style="list-style-type: none"> No breaches of the <i>Prohibition of Human Cloning for Reproduction Act 2002</i> were detected.
Research Involving Human Embryos Act 2002 Findings	<ul style="list-style-type: none"> No breaches of the <i>Research Involving Human Embryos Act 2002</i> were detected.
Compliance Status	Compliant

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 revised version of the information kit, developed to assist interested parties in understanding the legislation and the licensing process, was published during the reporting period. NHMRC released the updated kit at the Fertility Society of Australia annual conference in October 2008. The NHMRC also presented at the conference on the operation of the national regulatory scheme.

The information kit can be accessed on the NHMRC website at www.nhmrc.gov.au

Information exchange meetings

During the reporting period the NHMRC conducted two meetings with licence applicants to provide guidance on the operation of the legislation and the application process.

Appendix A: Membership of the NHMRC Licensing Committee

During the reporting period, 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	20 March 2009	Extension of licence duration to 16 April 2011
309702A	Sydney IVF		
309702B	Sydney IVF		
309710	Sydney IVF	20 March 2009	Extension of licence duration to 7 May 2011
309701	Sydney IVF	20 March 2009	Variation of standard conditions to simplify and clarify several conditions. To avoid unintentional non-compliance. Delete 1001-1004, 2102, 3101-3104. Add 1101, 3105 Modify 3001, 4201, 5001.
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	20 March 2009	Relocation of a condition which only applies to licences permitting the use of excess ART embryos. Delete 4001 from Standard Conditions (from all licences) and add it to Special Conditions of relevant licences.
309702A	Sydney IVF		
309702B	Sydney IVF		
309703	Sydney IVF		
309704	Melbourne IVF		
309709	Melbourne IVF		
309710	Sydney IVF		

Licence No.	Organisation	Date of variation	Brief description of variation
309701	Sydney IVF	20 March 2009	Change method of referring to authorised people. Add "Attachment A", listing all persons authorised to conduct the licensed activity.
309702A	Sydney IVF		
309702B	Sydney IVF		
309703	Sydney IVF		
309704	Melbourne IVF		
309709	Melbourne IVF		
309710	Sydney IVF		
309701	Sydney IVF	20 March 2009	Variation of special conditions to refer to "Attachment A" (see above). Modify 9301 and 9302.
309702A	Sydney IVF		
309702B	Sydney IVF		
309703	Sydney IVF		
309704	Melbourne IVF		
309709	Melbourne IVF		
309710	Sydney IVF		
309701	Sydney IVF	20 March 2009	Include a table showing variation history. Add "Table of Variations".
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 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.

At the end of the reporting period, Victoria, New South Wales, Tasmania, Queensland, the ACT and South Australia had 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

Fertility Treatment Amendment Act 2007

New South Wales

Human Cloning and Other Prohibited Practices Amendment Act 2007

Tasmania

Human Cloning and Other Prohibited Practices Amendment Act 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