



Australian Government

National Health and
Medical Research Council

N H M R C

Research Involving Human Embryos Act 2002

Embryo Research Licensing Committee of the NHMRC

LICENCE

This licence is issued under s.21 of the *Research Involving Human Embryos Act 2002*. This licence authorises the use of excess ART embryos specified below, subject to the conditions specified in items 8 and 9 below.

1. Licence number:	309702A
2. Licence holder:	Genea Limited
3. Licence title:	Effect of an Additive on Embryo Culture: Analysis of Growth and Epigenetic Programming
4. Date of issue:	16 April 2004
5. Licence begins:	16 April 2004
6. Licence ends:	28 March 2012
7. Use of excess ART embryos authorised by the licence	Research on variation in embryo growth and methylation of DNA resulting from the variation of physiological conditions in culture for the purposes of improving the success of IVF procedures.
8. Standard conditions	All conditions that are specified in the document <i>Standard Conditions for Using Excess ART Embryos</i> as currently published on www.nhmrc.gov.au/embryo and as amended from time to time.
9. Special conditions:	All conditions that are specified in <i>the Special Conditions for Licence No. 309702A</i> .

Note:

The use under this licence of excess ART embryos is subject to the provisions of the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002*.

309702A – Licence and Special Conditions – version 19, 28 March 2012

WORKING TO BUILD A HEALTHY AUSTRALIA

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Research Involving Human Embryos Act 2002

Embryo Research Licensing Committee of the NHMRC

Special Conditions for Licence No. 309702A

Licence number:	309702A
Licence holder:	Genea Limited
Licence title:	Effect of an Additive on Embryo Culture: Analysis of Growth and Epigenetic Programming

The conditions that are specified below are the special conditions that apply to this licence. The *Special Conditions* operate in addition to all conditions identified in the *Standard Conditions for Using Excess ART Embryos*. The *Special Conditions* prevail where there is an inconsistency between a special condition and a standard condition.

Number of embryos

Condition number	Condition
9101	The licence holder may use 128 excess ART embryos which are suitable for the use authorised by the licence.
9102	To obtain the required number of suitable embryos, the licence holder is authorised to remove up to 170 excess ART embryos from cryostorage.
9103	When the 128 suitable excess ART embryos have been successfully thawed and used, the licence holder is not authorised to thaw any more excess ART embryos.
9105	In order to achieve the stated goals of this project, embryos used in the growth studies authorised by this licence may be analysed by the methods used in licence 309702B. For the removal of doubt, the embryos studied by these methods under this licence 309702A do not count towards the total number of embryos authorised in licence 309702B.

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9106 The inner cell masses from a combined total of no more than **20** embryos used in connection with either this licence 309702A or licence 309702B may be transferred to the use authorised by licence 309703. Such transfer must not compromise the scientific outcomes of either this licence 309702A or licence 309702B.

9107 The licence holder may not remove from cryostorage for the purpose of conducting the use authorised by the licence a greater number of excess ART embryos than the number specified in condition 9101.

Specified sites

*Condition
number*

Condition

9201 The licence holder must conduct the use authorised by the licence at the following site:
Genea Limited
321 Kent St
Sydney NSW 2000

9202 The licence holder must hold records (other than patient records) associated with the use authorised by the licence at the following sites:

Genea Limited
321 Kent St
Sydney NSW 2000

Filesaver Pty Ltd
2151 Castlereagh Road
Penrith NSW 2750

9203 The licence holder must hold patient records associated with the excess ART embryos used in accordance with this licence only at the following sites:

Genea Limited
321 Kent St
Sydney NSW 2000

Filesaver Pty Ltd
2151 Castlereagh Road
Penrith NSW 2750

Persons authorised to use excess ART embryos

<i>Condition number</i>	<i>Condition</i>
9301	<p>The Principal Supervisor is responsible for supervision of the activity authorised by the licence.</p> <p>The Principal Supervisor is that person identified at Attachment A to this licence.</p>
9302	<p>Only authorised personnel may conduct the activity authorised by this licence.</p> <p>The authorised personnel are the Principal Supervisor and those other persons identified at Attachment A to this licence.</p>

Other Conditions

9501	<p>The culture medium additive that may be used in accordance with this licence is that and only that identified at Section B Part 1 Item C of the application dated 11 September 2003 and lodged in accordance with s.20 of the <i>Research Involving Human Embryos Act 2002</i>.</p>
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Conditions relating to proper consent

9601	<p>From 27 January 2011, only the Participant Information and Consent Form provided on 31 December 2010 and approved by the Licensing Committee may be used for obtaining proper consent to use the excess ART embryos in the activities permitted by this licence.</p>
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Table of Variations

Date of Variation	Conditions Affected	Description of Changes
1 July 2004	9302	Removal of two authorised persons from list of authorised persons Addition of seven authorised persons
3 August 2004	9302	Removal of authorised person from list of authorised persons
3 August 2004 (version 2)*	9203	Change of address of Sydney IVF Launceston
8 December 2004	Not applicable	Changes to the consent documents
27 April 2005 (version 3)	9104	Deletion of condition to reflect operation of sunset clause
27 April 2005 (version 3)	9105, 9106	Addition of conditions to clarify authorised activities and links between licences
27 April 2005	Expiry date	Extension of licence to 16 April 2007
27 April 2005	4201	Addition of new standard condition
27 April 2005 (version 4)	9203	Change of address of Sydney IVF Canberra
27 May 2005 (version 5)	9203	Change of address of Sydney IVF Illawarra
14 December 2005	Not applicable	Changes to the consent documents to reflect operation of sunset clause
19 December 2005	3001, 5001	Variation of standard conditions to improve clarity
29 June 2006	3001	Variation of standard condition to require final report on licensed activity
21 September 2006	9302	Addition of five authorised persons
24 October 2006 (version 6)	9201-9203	Move from O'Connell St to Kent St
24 October 2006 (version 6)	9203	Change of address for Sydney IVF Canberra, correction of addresses for Sydney IVF Orange and Sydney IVF Lismore
6 March 2007 (version 7)	Expiry date	Extension of licence to 16 April 2009
6 March 2007 (version 7)	9203	Addition of site of records storage and correction of addresses for Sydney IVF Coffs Harbour and Sydney IVF Launceston
15 May 2007	9302	Removal of authorised person from list of authorised persons
8 October 2007 (version 8)	9202, 9203	Addition of site of records storage
8 October 2007 (version 8)	9203	Change of address for Sydney IVF Canberra
4 December 2007	9302	Removal of two authorised persons from list of authorised persons

Date of Variation	Conditions Affected	Description of Changes
28 March 2008 (version 9)	9202, 9203	Removal of site of records storage, addition of new site of records storage
21 April 2008	9302	Removal of authorised person from list of authorised persons
21 August 2008	9302	Addition of an authorised person
28 August 2008	2001, 2301, 3001, 3101, 3102, 3104, 3201, 3401, 3601, 4001, 4002, 4101, 4102, 4201, 5001	Standard conditions varied to reflect the <i>Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006</i>
20 March 2009 (version 10)	Delete 1001-1004, 2102, 3101-3104, 4001 Add 1101, 3105, 9107, Table of Variations Vary 3001, 4201, 5001, 9301, 9302	Standard Conditions and Special Conditions varied to simplify and clarify requirements
20 March 2009 (version 10)	Expiry Date	Extension of licence to 16 April 2011
2 June 2009 (version 11)	9302	Removal of authorised person from list of authorised persons
27 July 2009 (version 12)	3001, 9401	Standard Conditions and Special Conditions varied to implement revised reporting periods
6 November 2009 (version 13)	9302	Removal of authorised person from list of authorised persons
15 April 2010 (version 14)	9401	Condition deleted. Revised reporting periods now in operation.
15 April 2010 (version 14)	9203	Addition of site of records storage
15 April 2010 (version 14)	5002, 6001, 6002	Standard Conditions varied to clarify requirements
27 January 2011 (version 15)	9601	Variation to the documents used for obtaining proper consent
27 January 2011 (version 15)	9302	Removal of authorised persons from list of authorised persons
13 April 2011 (version 16)	Expiry Date	Extension of licence to 31 December 2011
13 April 2011 (version 16)	9302	Removal of authorised person from list of authorised persons
19 May 2011 (version 17)	9601	Variation to the documents used for obtaining proper consent
1 December 2011 (version 18)	Licence Holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea
1 December 2011 (version 18)	9203	Removal of sites of records storage
1 December 2011 (version 18)	Expiry Date	Extension of licence to 31 March 2012
28 March 2012 (version 19)	Expiry date	Vary expiry date to coincide with issue of Licence 309719

* Where a variation resulted in a new version of the licence being issued, the version number is indicated.