Australian Government
National Health and Medical Research Council
NHMRC

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:	309701
2.	Licence holder:	Genea Limited
3.	Licence title:	Improvement in Laboratory Conditions for Embryo Culture
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 resulting from variation in physiological conditions in culture for the purposes of improving the success of IVF procedures. Embryos from this research may be used under Licence No. 309702B or Licence No. 309703 if they meet the conditions for those licences.
8.	Standard conditions	All conditions that are specified in the document *Standard Conditions for Using Excess ART Embryos* 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 the *Special Conditions for Licence No. 309701*.

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*.

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Research Involving Human Embryos Act 2002

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Special Conditions for Licence No. 309701

Licence number:	309701
Licence holder:	Genea Limited
Licence title:	Improvement in Laboratory Conditions for Embryo Culture

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 512 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 670 excess ART embryos from cryostorage.
9103	When the 512 suitable excess ART embryos have been successfully thawed and used the licence holder is not authorised to thaw any more excess ART embryos.
9104	Of the 512 excess ART embryos that the licence holder is authorised by Licence No. 309701 to use, 170 may subsequently be used in accordance with Licence No. 309702B.

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9105	If excess ART embryos thawed in connection with this licence are subsequently used in Licence No. 309702B, the records relating to the excess ART embryos must reflect their use in Licences 309701 and 309702B.
9106	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

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

Reporting

9401	If, at any time during the period of licence, interim analysis indicates that the use authorised by this licence may damage or destroy excess ART embryos, the licence holder must immediately cease the use and report this outcome to the NHMRC Licensing Committee within 3 days.

Other Conditions

9501	The culture medium additives that may be used in accordance with this licence are those and only those identified in Section D Part 1 and Appendix 1, pages 6 to 10 of the application dated 11 September 2003 and lodged in accordance with s.20 of the *Research Involving Human Embryos Act 2002*.
9502	The preliminary experiments with mice to demonstrate that the culture medium additives provide the expected benefit must be completed and reported to the Licensing Committee before testing with excess ART embryos can commence.

Conditions relating to proper consent

9601	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.

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, 9401	Changes to conditions to reflect operation of sunset clause
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
24 November 2005 (version 6)	9104, 9105	Variation required as a result of variation to Licence 309703
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 7)	9201-9203	Move from O'Connell St to Kent St
24 October 2006 (version 7)	9203	Change of address for Sydney IVF Canberra, correction of addresses for Sydney IVF Orange and Sydney IVF Lismore
6 March 2007 (version 8)	Expiry date	Extension of licence to 16 April 2009
6 March 2007 (version 8)	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

Date of Variation	Conditions Affected	Description of Changes
8 October 2007 (version 9)	9202, 9203	Addition of site of records storage
8 October 2007 (version 9)	9203	Change of address for Sydney IVF Canberra
4 December 2007	9302	Removal of two authorised persons from list of authorised persons
28 March 2008 (version 10)	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 *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*
20 March 2009 (version 11)	Delete 1001-1004, 2102, 3101-3104, 4001 Add 1101, 3105, 9106, Table of Variations Vary 3001, 4201, 5001, 9301, 9302	Standard Conditions and Special Conditions varied to simplify and clarify requirements
20 March 2009 (version 11)	Expiry Date	Extension of licence to 16 April 2011
2 June 2009 (version 12)	9302	Removal of authorised person from list of authorised persons
27 July 2009 (version 13)	3001, 9402	Standard Conditions and Special Conditions varied to implement revised reporting periods
6 November 2009 (version 14)	9302	Removal of authorised person from list of authorised persons
15 April 2010 (version 15)	9402	Condition deleted. Revised reporting periods now in operation.
15 April 2010 (version 15)	9203	Addition of site of records storage
15 April 2010 (version 15)	5002, 6001, 6002	Standard Conditions varied to clarify requirements
27 January 2011 (version 16)	9601	Variation to the documents used for obtaining proper consent
27 January 2011 (version 16)	9302	Removal of authorised persons from list of authorised persons
13 April 2011 (version 17)	Expiry Date	Extension of Licence to 31 December 2011

13 April 2011 (version 17)	9302	Removal of authorised person from list of authorised persons
19 May 2011 (version 18)	9601	Variation to the documents used for obtaining proper consent
1 December 2011 (version 19)	Licence Holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea
1 December 2011 (version 19)	9203	Removal of sites of records storage
1 December 2011 (version 19)	Expiry date	Extension of Licence to 31 March 2012
28 March 2012 (version 20)	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.