



Australian Government
National Health and Medical Research Council

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 activity specified below, subject to the conditions specified in items 9 and 10 below.

1.	Licence Number:	309702B
2.	Licence Holder:	Genea Limited
3.	Licence Title:	Development of Methods for Preimplantation Genetic and Metabolic Evaluation of Human Embryos
4.	Date of Issue:	16 April 2004
5.	Licence begins:	16 April 2004
6.	Licence ends:	16 April 2019
7.	Use of excess ART embryos authorised by the licence	Research to improve or develop methods for the genetic characterisation of embryos <i>in-vitro</i> , including chromosomal analysis, gene mutations, polymorphisms and epigenetic patterns, to better understand embryo metabolism and the processes of epigenetic programming.
8.	Goals of Activity	To improve IVF outcomes by developing test procedures that help identify embryos most likely to lead to a successful pregnancy.
9.	Standard Conditions:	All conditions that are specified in the document <i>Standard Conditions of Licence</i> as currently published on http://www.nhmrc.gov.au/health-ethics/human-embryos-and-cloning/database-licences-authorising-use-excess-art-embryos and as amended from time to time.
10.	Special Conditions:	All conditions that are specified in the <i>Special Conditions for Licence 309702B</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*. Terms used in this licence which are defined in those Acts carry the same meanings as they do in those Acts.



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Special Conditions for Licence 309702B

Licence Number:	309702B
Licence Holder:	Genea Limited
Licence Title:	Development of Methods for Preimplantation Genetic and Metabolic Evaluation of Human Embryos

The conditions that are specified below are the special conditions that apply to this licence. The *Special Conditions* operate **in addition to** conditions set out in s.24 of the *Research Involving Human Embryos Act 2002* (the statutory conditions) and all conditions identified in the *Standard Conditions of Licence*. The *Special Conditions* prevail where there is an inconsistency between a special condition and a standard condition.

Number of embryos

<i>Condition Number</i>	<i>Condition</i>
9101	The licence holder is authorised to use up to 220 excess ART embryos.
9105	The inner cell masses from 20 embryos used in connection with this licence may be transferred to the use authorised by Licence 309703. Such transfer must not compromise the scientific outcomes of this licence.
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

<i>Condition Number</i>	<i>Condition</i>
9201	The licence holder must conduct the use authorised by the licence at the following sites: 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 the 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 and Attachment B to this licence.</p>
9303	<p>A person identified in Attachment B to this licence may receive training under the licence as authorised by Condition 9701. The person is an authorised person under the licence but must be supervised when using any technique listed against the person's name in Attachment B.</p>

Reporting

9401	<p>At the same time as lodging each report required by the <i>Standard Conditions of Licence</i> (condition no. 3001), the licence holder must indicate which methods of analysis have been used for and how many cells have been removed from each embryo studied. The experimental methods listed in the licence application dated 11 September 2003 and in the letter dated 20 July 2011, and lodged in accordance with s.20 of the <i>Research Involving Human Embryos Act 2002</i> refer.</p>
9402	<p>When providing the reports required by Standard Condition 3001, the licence holder must identify any excess ART embryos that, in addition to their use in the activity authorised by Item 7, have been used for training activities as allowed by Condition 9701.</p>

Conditions relating to proper consent

<i>Condition Number</i>	<i>Condition</i>
9602	<p>Amendments to the consent process are permitted, provided the licence holder ensures that the consent process remains consistent with the <i>Consent checklist for licensed activities using excess ART embryos</i> available from www.nhmrc.gov.au. This replaces the requirements of Standard Condition 5002.</p>
9603	<p>Amendments to the <i>Participant Information and Consent Form</i> for Licence 309702B are permitted provided the licence holder ensures that the documents remain consistent with the <i>Consent checklist for licensed activities using excess ART embryos</i> available from www.nhmrc.gov.au. This replaces the requirements of Standard Condition 5002.</p>
9604	<p>When requested, the licence holder is required to provide copies of the documents currently in use to NHMRC inspectors for assessment of compliance with the licence conditions, applicable guidelines and consent checklist.</p>
9605	<p>An excess ART embryo may only be used for the training activities allowed by Condition 9701 if the people responsible for the embryo have given consent for its use in the training activities in addition to consent for the activities authorised by Item 7.</p>

Training activities included in licensed activity

<i>Condition Number</i>	<i>Condition</i>
9701	When excess ART embryos are used in the activity authorised by Item 7 and the activity involves the use of a technique for which a person identified in <u>Attachment B</u> requires training, the use of that technique may be used as a training activity.
9702	When receiving training in accordance with condition 9701, the person identified in <u>Attachment B</u> must be supervised at all times by an authorised person identified in <u>Attachment A</u> .

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
8 December 2004 (version 3)	9105, 9401	Addition of condition to clarify authorised activities and links between licences, change to condition to clarify reporting requirements
27 April 2005 (version 4)	9102	Deletion of condition 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 5)	9203	Change of address of Sydney IVF Canberra
27 May 2005 (version 6)	9203	Change of address of Sydney IVF Illawarra
24 November 2005 (version 7)	9101, 9103, 9105	Variation to number of embryos authorised to be used under the licence
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 8)	9201-9203	Move from O'Connell St to Kent St
24 October 2006 (version 8)	9203	Change of address for Sydney IVF Canberra, correction of addresses for Sydney IVF Orange and Sydney IVF Lismore
6 March 2007 (version 9)	Expiry date	Extension of licence to 16 April 2009
6 March 2007 (version 9)	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 10)	9202, 9203	Addition of site of records storage
8 October 2007 (version 10)	9203	Change of address for Sydney IVF Canberra

Date of Variation	Conditions Affected	Description of Changes
4 December 2007	9302	Removal of two authorised persons from list of authorised persons
28 March 2008 (version 11)	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 12)	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 12)	Expiry Date	Extension of licence to 16 April 2011
2 June 2009 (version 13)	9302	Removal of authorised person from list of authorised persons
27 July 2009 (version 14)	3001, 9402	Standard Conditions and Special Conditions varied to implement revised reporting periods
6 November 2009 (version 15)	9302	Removal of authorised person from list of authorised persons
15 April 2010 (version 16)	9402	Condition deleted. Revised reporting periods now in operation.
15 April 2010 (version 16)	9203	Addition of site of records storage
15 April 2010 (version 16)	5002, 6001, 6002	Standard Conditions varied to clarify requirements
27 January 2011 (version 17)	9601	Variation to the documents used for obtaining proper consent
27 January 2011 (version 17)	9302	Removal of authorised persons from list of authorised persons
13 April 2011 (version 18)	Expiry Date	Extension of licence to 31 December 2011
13 April 2011 (version 18)	9302	Removal of authorised persons from list of authorised persons
19 May 2011 (version 19)	9601	Variation to the documents used for obtaining proper consent
31 August 2011 (version 20)	Expiry Date	Extension of licence to 16 April 2014

Date of Variation	Conditions Affected	Description of Changes
31 August 2011 (version 20)	9103, 9104, 9105 9401 9601	Amendment of licence conditions consequent on the reorganisation of Sydney IVF licences for development of media and methods of embryo assessment
1 December 2011 (version 21)	Licence Holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea
1 December 2011 (version 21)	9601	Variation to the documents used to obtain proper consent following the company name change
1 December 2011 (version 21)	9203	Removal of sites of records storage
8 August 2013 (version 22)	9601	Variation to the documents used for obtaining proper consent
8 August 2013 (version 22)		Update licence to reflect Sydney IVF's name change to Genea Limited
14 April 2014 (version 23)	Expiry date	Extension of licence to 16 July 2014
14 April 2014 (version 23)	9302	Removal of authorised persons from list of authorised persons
26 June 2014 (version 24)	Expiry date	Extension of licence to 16 April 2017
27 August 2014 (version 25)	2301, 2302, 4301	Variation to Standard Conditions of Licence
1 October 2014 (version 26)	9301	New Principal Supervisor and Alternate Principal Supervisor
25 November 2015 (version 27)	9301	New Principal Supervisor and Alternate Principal Supervisor
9 March 2016 (version 28)	9601, 9602-9604	Variation to process for obtaining proper consent
6 April 2016 (version 29)	9201-9203	Addition of new site for licensed activity and records storage
6 June 2016 (version 30)	9302	Removal of authorised person from list of authorised persons
6 October 2016 (version 31)	9302	Removal of authorised persons from list of authorised persons
8 March 2017 (version 32)	Expiry date	Extension of licence to 16 April 2019
8 March 2017 (version 32)	9201-9203	Removal of site for licensed activity and records storage
7 June 2017 (version 33)	9301	Departure of Principal Supervisor and Alternate Principal Supervisor
7 June 2017 (version 33)	9301	New Principal Supervisor and Alternate Principal Supervisor

Date of Variation	Conditions Affected	Description of Changes
7 June 2017 (version 33)	9302, 9303 9402 9605 9701, 9702	Addition of conditions relating to training of authorised persons Changes to reporting requirements Requirement to obtain consent Approval of training activities within licensed activity
7 June 2017 (version 33)	9302	Removal of authorised person from list of authorised persons
7 June 2017 (version 33)	9302	Addition of authorised persons
6 November 2017 (version 34)	9302	Addition of authorised persons
11 December 2018 (version 35)	9302	Removal of authorised person from list of authorised persons
11 December 2018 (version 35)	9302	Addition of authorised person

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