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 8 and 9 below.

1.	Licence Number:	309703
2.	Licence Holder:	Genea Limited
3:	Licence Title:	Development of Human Embryonic Stem (ES) Cells
4.	Date of Issue:	16 April 2004
5.	Licence begins:	16 April 2004
6.	Licence ends:	14 February 2023
7.	Use of excess ART embryos authorised by the licence:	To isolate human embryonic stem cells from excess ART embryos for use in research into diagnosis and eventually for the treatment of human diseases such as juvenile diabetes and Parkinson's Disease.
8.	Standard conditions	All conditions that are specified in the document *Standard Conditions of Licence* 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.
9.	Special Conditions	All conditions that are specified in the *Special Conditions of Licence No. 309703*.

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 309703

Licence Number:	309703
Licence Holder:	Genea Limited
Licence Title:	Development of Human Embryonic Stem (ES) Cells

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 of Licence*. 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 is authorised to use up to 50 excess ART embryos.
9105	Up to 20 inner cell masses which have been derived pursuant to either Licence 309702A or Licence 309702B may be used for the purposes of this licence 309703 and if any inner cell masses are so used the excess ART embryos from which those inner cell masses have been derived are in addition to the 50 embryos authorised in condition 9101 of this licence.
9106	The records relating to any excess ART embryos used as permitted by condition 9105 must reflect their use in either 309702A and 309703 or 309702B and 309703.
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.

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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

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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** and **Attachment B** to this licence.
9303	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**.

Reporting

Condition Number	*Condition*
9401	The licence holder must report progress on establishing embryonic stem cell lines to the NHMRC Licensing Committee in writing when 25 of the 50 excess ART embryos authorised in condition 9101 have been used.
9402	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.

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Number of embryos

Condition Number	*Condition*
9501	The licence holder is authorised to use up to 150 excess ART embryos in addition to those authorised in condition 9101.
9502	The use of the additional excess ART embryos authorised by condition 9501 and the use of the inner cell masses authorised by condition 9105 is permitted for the following experiments: (a) new methods of containing or separating outgrowing inner cell mass cells; (b) changes in the environment used for human embryonic stem cell line derivation; (c) evaluation of feeder-free matrices in derivation of human embryonic stem cell lines; (d) evaluation of variations in culture medium constituents; (e) evaluation of substitutions for animal-sourced protein-based supplements or growth factors; and (f) evaluation of epigenetic modifiers.
9503	The substances and conditions to be tested in experiments (b) to (f) listed in Condition 9502 must first have been tested on embryonic stem cell lines for absence of detriment or for improvement (as judged by one of the licence holder's scientists).

Reporting

Condition Number	*Condition*
9504	Within 30 days of completion of each set of experiments outlined in Condition 9502, the licence holder must report in writing on the outcome of that set of experiments to the NHMRC Licensing Committee.

Number of embryos

Condition Number	*Condition*
9505	The licence holder is authorised to use up to 100 embryos in addition to those authorised in conditions 9101 and 9501.

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Conditions relating to proper consent

Condition Number	*Condition*
9602	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.
9603	Amendments to the consent process are permitted, provided the licence holder ensures that the consent process remains consistent with the *Consent checklist for licensed activities using excess ART embryos* available from www.nhmrc.gov.au. This replaces the requirements of Standard Condition 5002.
9604	Amendments to the *Participant Information and Consent Form for Licence 309703* are permitted provided the licence holder ensures that the documents remain consistent with the *Consent checklist for licensed activities using excess ART embryos* available from www.nhmrc.gov.au. This replaces the requirements of Standard Condition 5002.
9605	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.

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Training activities included in licensed activity

Condition Number	*Condition*
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 **Attachment B** 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 **Attachment B** must be supervised at all times by an authorised person identified in **Attachment A**.

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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 (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, 9106	Addition of condition to permit transfer of inner cell masses from Licence 309702A and 309702B
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
21 September 2005 (version 7)	9201, 9202	Add Q-Gen Pty Ltd as site of authorised activity
6 October 2005	Not applicable	Changes to consent documents
24 November 2005 (version 8)	9103, 9104	Deletion of conditions relating to transfer of embryos between licences
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
29 June 2009 (version 9)	9402	Addition of special condition requiring post-expiry report.
21 September 2006	9302	Addition of five authorised persons
24 October 2006 (version 10)	9201-9203	Move from O'Connell St to Kent St
24 October 2006 (version 10)	9203	Change of address for Sydney IVF Canberra, correction of addresses for Sydney IVF Orange and Sydney IVF Lismore
28 March 2007 (version 11)	Expiry date	Extension of licence to 16 April 2009

Expired

28 March 2007 (version 11)	9203, 9302	Addition of site of records storage and correction of addresses for Sydney IVF Coffs Harbour and Sydney IVF Launceston, correct reference to document listing authorised persons
15 May 2007	9302	Removal of authorised person from list of authorised persons
8 October 2007 (version 12)	9202, 9203	Addition of site of records storage
8 October 2007 (version 12)	9203	Change of address for Sydney IVF Canberra
4 December 2007	9302	Removal of two authorised persons from list of authorised persons
4 January 2008 (version 13)	Expiry date	Extend to 16 April 2010
4 January 2008 (version 13)	9501-9504	Addition of new conditions to increase the number of embryos authorised for use, vary the details of the authorised activity and change the reporting conditions
28 March 2008 (version 14)	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 15)	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
2 June 2009 (version 16)	9302	Removal of authorised person from list of authorised persons
27 July 2009 (version 17)	3001, 9403	Standard Conditions and Special Conditions varied to implement revised reporting periods
6 November 2009 (version 18)	9302	Removal of authorised person from list of authorised persons
15 April 2010 (version 19)	9403	Condition deleted. Revised reporting periods now in operation.
15 April 2010 (version 19)	9203	Addition of new site of records storage
15 April 2010 (version 19)	5002, 6001, 6002	Standard Conditions varied to clarify requirements

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15 April 2010 (version 19)	Expiry date	Extend to 16 April 2012
20 May 2010 (version 20)	9505	Addition of new condition to increase the number of embryos authorised for use
27 January 2011 (version 21)	9601	Variation to the documents used for obtaining proper consent
27 January 2011 (version 21)	9302	Removal of authorised person from list of authorised persons
13 April 2011 (version 22)	9201, 9202	Removal of site from lists of authorised sites for conduct of authorised activity and records storage
19 May 2011 (version 23)	9601	Variation to the documents used for obtaining proper consent
1 December 2011 (version 24)	Licence Holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea
1 December 2011 (version 24)	9601	Variation to the documents used to obtain proper consent following the company name change
1 December 2011 (version 24)	9203	Removal of sites of records storage
20 March 2012 (version 25)	Expiry date	Extend to 16 April 2014
20 March 2012 (version 25)	9502	Vary the details of experiments authorised by the licence
12 June 2012 (version 26)	9302	Addition of authorised persons
12 June 2012 (version 26)	Licence holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea Limited
8 May 2013 (version 27)	9402	Removal of reporting condition
8 August 2013 (version 28)	9601	Variation to the documents used for obtaining proper consent
14 April 2014 (version 29)	Expiry date	Extension of licence to 16 July 2014
14 April 2014 (version 29)	9302	Removal of authorised person from list of authorised persons
26 June 2014 (version 30)	Expiry date	Extension of licence to 16 April 2017
26 June 2014 (version 30)	Attachment A	Removal of condition relating to an authorised person's use of excess ART embryos
27 August 2014 (version 31)	2301, 2302, 4301	Variation to Standard Conditions of Licence
1 October 2014 (version 32)	9301	New Principal Supervisor and Alternate Principal Supervisor
1 October 2014 (version 32)	9302	Addition of authorised person

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30 June 2015 (version 33)	9302, 9303 9402 9602 9701, 9702	Addition of authorised persons Changes to reporting conditions Requirement to obtain consent Approval of training activities within licensed activity
25 November 2015 (version 34)	9302	Removal of authorised person from list of authorised persons
9 March 2016 (version 35)	9302, 9303	Addition of authorised person
9 March 2016 (version 35)	9303	Approval of additional techniques
9 March 2016 (version 35)	9601, 9603-9605	Variation to process for obtaining proper consent
6 June 2016 (version 36)	9302	Removal of authorised person from list of authorised persons
6 June 2016 (version 36)	9302, 9303	Removal of authorised person from list of authorised persons
6 October 2016 (version 37)	9302	Removal of authorised person from list of authorised persons
8 March 2017 (version 38)	Expiry date	Extension of licence to 16 April 2019
8 March 2017 (version 38)	9302	Removal of authorised person from list of authorised persons
7 June 2017 (version 39)	9301	Departure of Alternate Principal Supervisor
7 June 2017 (version 39)	9301	New Alternate Principal Supervisor
7 June 2017 (version 39)	9302	Removal of authorised person from list of authorised persons
28 February 2018 (version 40)	9302	Removal of authorised person from list of authorised persons
14 June 2018 (version 41)	9301	Departure of Principal Supervisor
14 June 2018 (version 41)	9301	New Principal Supervisor
15 April 2019 (version 42)	Expiry date	Extension of licence to 16 April 2022
10 January 2020 (version 43)	9301	Removal of Alternate Principal Supervisor
13 April 2022 (version 44)	Expiry date	Extension of licence to 2 June 2022
31 May 2022 (version 45)	Expiry date	Extension of licence to 2 December 2022
1 December 2022 (version 46)	Expiry date	Extension of licence to 14 February 2023
20 December 2022 (version 47)	9301	Removal of 2 authorised persons

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

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