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:	309710
2.	Licence Holder:	Genea Limited
3:	Licence Title:	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known serious monogenic conditions
4.	Date of Issue:	7 May 2007
5.	Licence begins:	7 May 2007
6.	Licence ends:	2 June 2022
7.	Use of excess ART embryos authorised by the licence:	This licence authorises, subject to the Standard Conditions and the Special Conditions, the following uses of excess ART embryos: The derivation of human embryonic stem cell (hESC) lines from cryostored embryos which have been identified by preimplantation genetic diagnosis (PGD) as being embryos affected by a serious monogenic condition. The hESC lines will be used for the conduct of collaborative research into the molecular biology of serious familial diseases, the development of treatments for the genetic conditions concerned, and the development and testing of drugs.
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 for Licence No. 309710*.

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 No. 309710

Licence Number:	309710
Licence Holder:	Genea Limited
Licence Title:	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known serious monogenic conditions

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.

Conditions relating to embryos

Condition Number	*Condition*
9101	The licence holder is authorised to use up to 500 excess ART embryos.
9102	Embryos used for the activities authorised by this licence are used following a period of cryostorage.
9103	This licence is limited to the use of embryos which have been identified by preimplantation genetic diagnosis to have a serious monogenic condition, consistent with the requirements outlined in the NHMRC *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2007*.
9105	Stem cell lines established under this licence count towards the limit stipulated in Condition 9109 when they meet the following criteria: • the embryonic stem cell line possesses a stable human diploid karyotype, expresses immunologically defined markers and genes specific for embryonic stem cells; • results from initial studies indicate that the cell line is pluripotent and capable of self-renewal; • the line has been passaged at least five times in culture, and has been successfully cryopreserved and thawed on two occasions; and • the line has been demonstrated to be free of contamination by adventitious agents.
9106	When eight embryonic stem cell lines have been established in accordance with conditions 9105 and 9109, any remaining cell lines under evaluation may, subject to condition 9402, be used in accordance with the licence.

9107	Excess ART embryos with chromosomal anomalies (eg. monosomies, trisomies and translocations) are not permitted to be used under this licence, with the exception of specified chromosomal anomalies notified to, and authorised by, the Licensing Committee.
9108	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.
9109	The licence holder is authorised to establish up to eight stem cell lines for each serious monogenic condition.
9110	When eight stem cell lines with an individual serious monogenic condition have been established, no further excess ART embryos identified as having this condition may be used under this licence.

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 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** and **Attachment B** to this licence.
9302	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*
9402	(a) The licence holder must notify the Licensing Committee in writing within five (5) working days when the combined total of established and potential embryonic stem cell lines with an individual serious monogenic condition equals or exceeds eight. (b) The licence holder must notify the Licensing Committee in writing within five (5) working days when the number of established embryonic stem cell lines per individual serious monogenic condition equals or exceeds eight.
9403	When providing the reports required by Standard Condition 3001, the licence holder must report on the nature of the monogenic condition affecting each embryo used.
9404	When providing the reports required by Standard Condition 3001, the licence holder is required to report on success in establishing embryonic stem cell lines according to the criteria set out in condition 9105.
9405	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.

Conditions relating to proper consent

Condition Number	*Condition*
9503	When embryos are cryostored before use under the licence a cooling-off period of at least two weeks must be observed.
9507	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.
9508	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.
9509	Amendments to the *Participant Information and Consent Form for Licence 309710* and the *Declaration of excess PGD embryos* form 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.
9510	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.

Training activities included in licensed activity

Condition Number	*Condition*
9701	When an excess ART embryo is used in the activity authorised by Item 7 and use of the embryo involves 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**.

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
8 October 2007 (version 2)*	9202, 9203	Addition a site of records storage
8 October 2007 (version 2)	9203	change of Sydney IVF Canberra address
4 December 2007	9302	Removal of two authorised person from list of authorised persons
28 March 2008 (version 3)	9202, 9203	Removal of site of records storage, addition of new site of records storage
21 April 2008	9302	Removal of authorised person
16 June 2008 (version 4)	Item 7 9102, 9105 New 9501 - 9504	Permission to use non-cryostored embryos
21 August 2008	9302	Addition of authorised person from list of authorised persons
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 5)	Delete 1001-1004, 2102, 3101-3104, 4001 Add 1101, 3105, 9108 Vary 3001, 4201, 5001, 9301, 9302	Standard Conditions and Special Conditions varied to simplify and clarify requirements
20 March 2009 (version 5)	Expiry Date	Extension of licence to 7 May 2011
2 June 2009 (version 6)	9302	Removal of authorised person from list of authorised persons
27 July 2009 (version 7)	3001, 9406	Standard Conditions and Special Conditions varied to implement revised reporting periods
6 November 2009	9302	Removal of authorised person from list of authorised persons
13 November 2009 (version 8)	9101, 9103, 9104, 9105, 9106, 9402, 9402, 9403 Add 9109, 9110 Delete 9104, 9401, 9406.	Increase to permitted number of embryos; removal of limit to use of embryos diagnosed by PGD as having Huntington's Disease, Cystic Fibrosis or other serious genetic condition; removal of limit to number of stem cell lines permitted to be derived; addition of limit to number of stem cell lines per serious monogenic condition; modification of notification requirement relating to stem cell line limit.
15 April 2010 (version 9)	9203	Addition of site of records storage
15 April 2010 (version 9)	5002, 6001, 6002	Standard Conditions varied to clarify requirements
23 July 2010 (version 10.1)	9501, 9504, 9505	Variation to process for obtaining proper consent
27 January 2011 (version 11)	9501, 9505	Variation to process and documents used for obtaining proper consent

27 January 2011 (version 11)	9302	Removal of authorised person from list of authorised persons
21 March 2011 (version 11.3)	9505	Variation to documents used for obtaining proper consent
14 April 2011 (version 12)	Expiry Date	Extension of licence to 7 May 2013
14 April 2011 (version 12)	9302	Removal of authorised person from list of authorised persons
14 April 2011 (version 12)	9501	Variation to process for obtaining proper consent
20 June 2011 (version 13)	9105	Variation to criteria for established embryonic stem cell lines
1 December 2011 (version 14)	Licence Holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea
1 December 2011 (version 14)	9505	Variation to the documents used to obtain proper consent following the company name change
1 December 2011 (version 14)	9203	Removal of sites of records storage
12 June 2012 (version 15)	9302	Addition of authorised persons
12 June 2012 (version 15)	Licence holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea Limited
20 March 2013 (version 16)	9505	Variation to documents used for obtaining proper consent
20 March 2013 (version 16)	Expiry Date	Extension of licence to 7 May 2016
8 May 2013 (version 17)	9505	Variation to documents used for obtaining proper consent
8 May 2013 (version 17)	9405	Removal of reporting condition
28 February 2014 (version 18)	9302	Removal of authorised person from list of authorised persons
26 June 2014 (version 19)	9101	Increase to permitted number of embryos
26 June 2014 (version 19)	Attachment A	Removal of condition relating to an authorised person's use of excess ART embryos
27 August 2014 (version 20)	2301, 2302, 4301	Variation to Standard Conditions of Licence
1 October 2014 (version 21)	9301	New Principal Supervisor and Alternate Principal Supervisor
1 October 2014 (version 21)	9302	Addition of authorised person
15 June 2015 (Version 22)	Item 7, 9102, 9502, 9504 9506	Removal of option to use non-cryostored embryos Clarification of consent process for cryostored embryos
30 June 2015 (Version 23)	9302, 9303 9405 9507 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 24)	9302	Removal of authorised person from list of authorised persons
9 March 2016 (Version 25)	9302, 9303	Addition of authorised person
9 March 2016 (Version 25)	9303	Approval of additional techniques
9 March 2016 (Version 25)	9505-9506, 9508-9510	Variation to process for obtaining proper consent
27 April 2016 (Version 26)	Expiry date	Extension of licence to 7 May 2019
6 June 2016 (Version 27)	9302	Removal of authorised person from list of authorised persons
6 June 2016 (Version 27)	9302, 9303	Removal of authorised person from list of authorised persons
6 October 2016 (Version 28)	9302	Removal of authorised person from list of authorised persons
8 March 2017 (Version 29)	9302	Removal of authorised person from list of authorised persons
7 June 2017 (Version 30)	9301	Departure of Alternate Principal Supervisor
7 June 2017 (Version 30)	9301	New Alternate Principal Supervisor
7 June 2017 (Version 30)	9302	Removal of authorised person from list of authorised persons
28 February 2018 (Version 31)	9302	Removal of authorised person from list of authorised persons
14 June 2018 (Version 32)	9301	Departure of Principal Supervisor
14 June 2018 (Version 32)	9301	New Principal Supervisor
15 April 2019 (Version 33)	Expiry date	Extension of licence to 7 May 2022
10 January 2020 (Version 34)	9301	Removal of Alternate Principal Supervisor
13 April 2022 (Version 35)	Expiry date	Extension of licence to 2 June 2022

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