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:	309713
2.	Licence Holder:	Genea Limited
3:	Licence Title:	Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs.
4.	Date of Issue:	16 September 2008
5.	Licence begins:	16 September 2008
6.	Licence ends:	16 December 2015
7.	Activity authorised by the licence:	The activities authorised by this licence are: • creation of human embryos using SCNT techniques and clinically unusable eggs; and • derivation of human embryonic stem cell lines from the human embryos created by SCNT. The human eggs to be used under this licence are those excluded from clinical use because they are either unsuitable for fertilisation or have failed to fertilise normally. Such eggs are therefore considered unsuitable for transfer to a woman during assisted reproductive technology (ART) treatment. The somatic cells permitted to be used under this licence will be adult human fibroblasts obtained during unrelated procedures in the licence holder's day surgery unit.
8.	Goals of the Activity:	The goals of the licensed activity are: • establish reproducible methods for the creation of human SCNT embryos; • demonstrate the feasibility of deriving embryonic stem cell lines from human SCNT embryos; and • establish reliable methods for the derivation of embryonic stem cell lines from human SCNT embryos.

Expired

9.	Standard Conditions:	All conditions that are specified in the *Standard Conditions of Licence*.
10.	Special Conditions:	All conditions that are specified in the *Special Conditions for Licence No. 309713*.

Note: The activity authorised under this licence 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.

Expired

Australian Government

National Health and Medical Research Council

Research Involving Human Embryos Act 2002

Embryo Research Licensing Committee of the NHMRC

Special Conditions for Licence 309713

Licence Number:	309713
Licence Holder:	Genea Limited
Licence Title:	Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs.

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.

Expired

Conditions relating to use of embryos

Condition Number	*Condition*
9101	The licence holder is authorised to use up to 2400 eggs which have been determined to be clinically unusable due to: (a) being assessed as immature, owing to the continued presence of the germinal vesicle or the absence of a polar body, and thus unsuitable for fertilisation by intracytoplasmic sperm injection not less than 6 hours after retrieval; *or* (b) the presence of 1 pronucleus or 3 pronuclei when examined not less than 14 hours after insemination; *or* (c) the continued presence of only one clear and distinct polar body and no evidence of pronuclei formation when examined not less than 14 hours after insemination; *and* which have been determined to be suitable (as judged by one of the licence holder's scientists) for use in the creation or attempted creation of embryos by the process of SCNT. For the purposes of this licence, "use" of the egg is deemed to commence at the beginning of preparation of the egg for the SCNT protocol, whatever that preparation may involve.
9102	The total of 2400 eggs does not include those eggs which have been donated to the research project but which have been determined to be unsuitable for the research.
9103	An outcome must be recorded for every egg donated to the research project, irrespective of whether the egg is used in the research project.
9104	If the licence holder has used 1600 eggs and no embryonic stem cell lines have been established, then no more eggs may be used.
9105	Only fibroblast cells obtained from women during laparoscopy procedures who have given consent to this use of their cells may be used as the source of nuclear deoxyribonucleic acid (DNA) for the SCNT embryos created under this licence.
9106	The licence holder is authorised to use the eggs specified in Condition 9101 and the nuclear DNA specified in Condition 9105 to create up to 360 embryos by the process of SCNT which then reach the blastocyst stage of development.
9107	If 160 blastocysts have been created and no embryonic stem cell lines have been established, then no more eggs may be used.
9108	The licence holder is authorised to establish up to 6 cloned human embryonic stem cell lines from the blastocysts created according to condition 9106.
9109	An embryonic stem cell line derived under this licence is considered to be established and will be counted as one of the 6 cloned embryonic stem cell lines authorised by Condition 9108 when it meets the following criteria: • the embryonic stem cell line must possess a stable human diploid karyotype, express 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 must have been passaged ten times in culture, successfully cryopreserved on two occasions and shown to be free of contamination by adventitious agents; and • the genetic identity of the cloned cell line has been demonstrated to be identical to the genetic identity of the donor nucleus.

Expired

9110	When 6 embryonic stem cell lines have been established in accordance with condition 9109, any remaining cell lines under evaluation may, subject to condition 9404, be used in accordance with the licence.
9111	If 480 embryos have been created and reach the 16-cell stage of development and no embryonic stem cell lines have been established, then no more eggs may be used.

Expired

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 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

Expired

Persons authorised to conduct the licensed activity

Condition Number	*Condition*
9301	The Principal Supervisor is responsible for supervision of the activity authorised by the licence. The Principal Supervisor is the 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

Condition Number	*Condition*
9402	The licence holder must report to the Licensing Committee within 14 days of the first time an SCNT embryo reaches the blastocyst stage of development.
9403	The licence holder must report to the Licensing Committee within 14 days of the first time an SCNT embryo results in an embryonic stem cell line that is able to be passaged for the third time following initial plating.
9404	The licence holder must report immediately in writing to the Licensing Committee in the following circumstances: (a) the combined total of: (i) the number of established cloned embryonic stem cell lines, being fewer than 6; and (ii) the number of potential cloned embryonic stem cell lines under investigation; exceeds 6; or (b) the number of established cloned embryonic stem cell lines equals or exceeds 6.
9405	When providing the reports required by Standard Condition 3001, the licence holder is required to report on success in creating blastocysts by SCNT and in establishing cloned embryonic stem cell lines according to the criteria set out in condition 9109 and on the genetic identity of the cell lines so created or established.
9406	When recording an outcome for each egg as required by Condition 9103, the licence holder is required to use the template specified in Standard Condition 3001.

Conditions relating to proper consent

Condition Number	*Condition*
9501	From 9 December 2013, the licence holder must not request consent to use clinically unusable eggs in accordance with this licence until a revised Participant Information and Consent Form document has been considered and approved by the Licensing Committee.

Expired

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
20 March 2009 (version 2)	Delete 1001-1004, 2102, 3101-3104, 4001 Add 1101, 3105, Table of Variations Vary 3001, 4201, 5001	Standard Conditions and Special Conditions varied to simplify and clarify requirements
27 July 2009 (version 3)	3001, 9407	Standard Conditions and Special Conditions varied to implement revised reporting periods
16 November 2009 (version 4)	5001	Minimum period between provision of patient information and seeking patient consent changed from four to two weeks; modifications to patient information booklet
15 April 2010 (version 5)	9407	Condition deleted. Revised reporting periods now in operation.
15 April 2010 (version 5)	9203	Addition of sites of records storage
15 April 2010 (version 5)	5002, 6001, 6002	Standard Conditions varied to clarify requirements
30 August 2010 (version 6)	9302	Addition of an authorised person
6 July 2011 (version 7)	9302	Addition of authorised persons
24 August 2011 (version 8)	Expiry date 9111	Extension of Licence, addition of end point condition
1 December 2011 (version 9)	Licence Holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea
1 December 2011 (version 9)	9203	Removal of sites of records storage
18 April 2012 (Version 10)	Licence holder, 9201-9203	Update licence to reflect Sydney IVF's name change to Genea Limited
18 April 2012 (Version 10)	Expiry date	Extension of licence
18 April 2012 (Version 10)	9302	Removal of authorised person from list of authorised persons
16 September 2013 (version 11)	Expiry date	Extension of licence
9 December 2013 (version 12)	Expiry date	Extension of licence
9 December 2013 (version 12)	9501	Addition of condition relating to obtaining consent
28 February 2014 (version 13)	9302	Removal of authorised person from list of authorised persons
27 August 2014 (version 14)	2301, 2302, 4301	Variation to Standard Conditions of Licence
17 December 2015 (version 14)		Expiry of Licence

Expired