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:	309719
2.	Licence Holder:	Genea Limited
3:	Licence Title:	Use of excess ART embryos for the development of improved IVF culture media
4.	Date of Issue:	28 March 2012
5.	Licence begins:	28 March 2012
6.	Licence ends:	28 March 2024
7.	Activity authorised by the licence:	This licence authorises the culture of excess ART embryos in new or varied conditions to assess the effect of these conditions on embryo growth and development. The embryos will not be deliberately destroyed during these experiments. Provided additional consent has been obtained, selected embryos from the embryo culture experiments will be analysed to assess the impact of the culture conditions on the genetic and epigenetic profiles of the embryos. This analysis will destroy the embryos. The embryos to be used under this licence are frozen embryos which have been declared to be excess to the reproductive needs of the responsible people concerned.
8.	Goals of the Activity:	The goals of the licensed activity are: • to develop improved embryo culture conditions for the purpose of improving the success of IVF procedures.
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. 309719*.

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.

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Special Conditions for Licence 309719

Licence Number:	309719
Licence Holder:	Genea Limited
Licence Title:	Use of excess ART embryos for the development of improved IVF culture media

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 use of embryos

Condition Number	*Condition*
9101	The licence holder is authorised to use up to 640 excess ART embryos to assess the effect of new or varied culture media on the growth and development of those embryos.
9102	The licence holder may not remove from cryostorage a greater number of excess ART embryos than the number specified in condition 9101 for the purpose of conducting the activity authorised by the licence.
9103	In order to assess the genetic and epigenetic profiles of the embryos and thus achieve the stated goals of this project, embryos used in the embryo culture experiments authorised by this licence may then be analysed by the methods used in Licence 309702B. The embryos studied by these methods under this Licence 309719 do not count towards the total number of embryos authorised in Licence 309702B.
9104	If excess ART embryos thawed in connection with this licence are subsequently studied by the methods authorised by Licence 309702B, the records relating to the excess ART embryos must reflect the additional use.
9105	Excess ART embryos that are not studied by the methods used in Licence 309702B shall be allowed to succumb at the conclusion of the embryo culture experiments.
9106	If, at any time during the period of the licence, interim analysis indicates that a culture medium additive or combination of culture medium additives used as authorised by this licence may be having a negative effect on the excess ART embryos, the licence holder must immediately cease the use of the culture medium additive or combination of culture medium additives.
9107	When the licence holder has determined that a particular compound or combination of compounds should be transferred to clinical evaluation or commercial production, no more excess ART embryos may be used to test that compound or combination of compounds.

Specified Sites

Condition Number	*Condition*
9201	The licence holder must conduct the use of excess ART embryos 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
9203	The licence holder must hold patient records associated with the licensed activity at the following sites: Genea Limited 321 Kent St Sydney NSW 2000 Filesaver Pty Ltd 2151 Castlereagh Road Penrith NSW 2750

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** 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 to the Licensing Committee within 14 days of determining that the situation described in Condition 9106 has occurred. The report must include an analysis of and reasons for the observed results. If the licence holder wishes to continue using excess ART embryos to investigate inclusion of the compound or combination of compounds referred to in the report in the development of culture media then the report must also include a justification for this activity. Use of embryos to continue testing the compound or combination of compounds may only commence after the Licensing Committee has approved the report.
9402	The licence holder must report to the Licensing Committee within 14 days of determining that inclusion of a particular compound or combination of compounds in culture media should be transferred to clinical evaluation or commercial production, whichever comes first.
9403	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	Analysis of the impact of the culture conditions on the genetic and epigenetic profiles of embryos in accordance with Condition 9103 may only be conducted if the persons responsible for the embryos have signed a consent form for Licence 309702B in addition to the consent form for Licence 309719.
9504	When cryostored excess ART embryos are used under the licence a “cooling-off” period of at least 2 weeks must be observed.
9505	From 1 October 2014, when excess ART embryos are being transported from external clinics to Genea Ltd for use under this licence, only the process approved by the Licensing Committee on 26 September 2014 may be used when obtaining consent for transport and proper consent for use of the embryos.
9506	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.
9507	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.
9508	Amendments to the *Participant Information and Consent Form for Licence 309719* 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.
9509	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.

Other conditions

Condition Number	*Condition*
9601	The use of a new culture medium additive or combination of additives may not commence until: (a) the licence holder has notified the Licensing Committee of the intention to use a new culture medium additive or combination of additives; *and* (b) the notification includes the identities and proposed range of test concentrations of the additives to be used and a summary of the literature and/or preliminary experiments using animal embryos or genetic studies that justify the choice of additives and concentrations; *and* (c) the Licensing Committee has approved the notification.

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**.

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
4 June 2012 (version 2)	9106	Reworded to clarify negative endpoint
4 June 2012 (version 2)	9108	Licence condition removed
8 August 2013 (version 3)	9502	Variation to the documents used for obtaining proper consent
28 February 2014 (version 4)	9301	New Principal Supervisor
26 June 2014 (version 5)	9505	Addition of condition relating to the process of obtaining proper consent to use excess ART embryos obtained from clinics outside Genea Ltd
26 June 2014 (version 5)	Attachment A	Removal of condition relating to an authorised person's use of excess ART embryos
27 August 2014 (version 6)	2301, 2302, 4301	Variation to Standard Conditions of Licence
1 October 2014 (version 7)	9301	Add Alternate Principal Supervisor
1 October 2014 (version 7)	9505	Variation to condition relating to the process of obtaining proper consent to use excess ART embryos obtained from clinics outside Genea Ltd
16 October 2014 (version 8)	9302	Addition of new authorised person
5 December 2014 (version 9)	Expiry date	Extension of licence to 28 March 2018
11 March 2015 (version 10)	9301	Removal of Alternate Principal Supervisor from list of authorised persons
18 January 2016 (version 11)	9301	New Alternate Principal Supervisor, variation to list of authorised persons
9 March 2016 (version 12)	9302, 9303 9403 9506 9701, 9702	Addition of authorised persons Changes to reporting conditions Requirement to obtain consent Approval of training activities within licensed activity
9 March 2016 (version 12)	9301	New Principal Supervisor
9 March 2016 (version 12)	9501-9502, 9507-9509	Variation to process for obtaining proper consent
6 April 2016 (version 13)	9201-9203	Addition of new site for licensed activity and records storage
21 April 2016 (version 14)	9302	Addition of new authorised person

6 June 2016 (version 15)	9302, 9303	Removal of authorised person from list of authorised persons
8 March 2017 (version 16)	9302	Removal of authorised person from list of authorised persons
8 March 2017 (version 16)	9201-9203	Removal of site for licensed activity and records storage
8 March 2017 (version 16)	9302	Addition of new authorised person
7 June 2017 (version 17)	9302	Removal of authorised people from list of authorised persons
6 December 2017 (version 18)	9302	Addition of new authorised persons
5 March 2018 (version 19)	Expiry date	Extension of licence to 28 March 2021
11 December 2018 (version 20)	9302	Removal of authorised person from list of authorised persons
11 December 2018 (version 20)	9302	Addition of new authorised person
10 January 2020 (version 21)	9302	Removal of authorised person from list of authorised persons
10 August 2020 (version 22)	9302	Removal of authorised persons from list of authorised persons
10 August 2020 (version 22)	9302	Addition of new authorised person
26 March 2021 (version 23)	Expiry date	Extension of licence to 30 June 2021
10 June 2021 (version 24)	Expiry date	Extension of licence to 28 March 2024
30 June 2021 (version 25)	9302	Removal of authorised persons from list of authorised persons
20 December 2022 (version 26)	9301	Departure of Principal Supervisor Approval of new Principal Supervisor
20 December 2022 (version 26)	9302	Removal of authorised persons