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:	309718
2.	Licence Holder:	Genea Limited
3:	Licence Title:	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device
4.	Date of Issue:	8 December 2011
5.	Licence begins:	8 December 2011
6.	Licence ends:	8 December 2021
7.	Activity authorised by the licence:	The activity authorised by this licence is: • Use of excess ART embryos and clinically unusable human eggs to validate an IVF device. The human eggs to be used under this licence are those excluded from clinical use because they have fertilised abnormally. Such eggs are therefore considered unsuitable for transfer to a woman during assisted reproductive technology (ART) treatment. 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 validate a device for freezing embryos which aims to reduce handling variability and improve embryo traceability and viability, thus reducing human errors and stress on the embryos, by using groups of 60 eggs (that is, 30 test and 30 control eggs) or 60 embryos (that is, 30 test and 30 control embryos) to test each set of parameters for confirmation or validation of the device.
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. 309718*.

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 309718

Licence Number:	309718
Licence Holder:	Genea Limited
Licence Title:	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device

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 eggs and creation of embryos

Condition Number	*Condition*
9101	The licence holder is authorised to use up to 1000 eggs which have been determined to be clinically unusable due to the presence of 1 pronucleus or 3 pronuclei 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 the activity authorised by this licence. For the purposes of this licence, abnormally fertilised eggs must be frozen following the determination that they are clinically unusable and use of each egg is deemed to commence when it is thawed following the period in frozen storage.
9102	An outcome must be recorded for every egg donated to the research project, irrespective of whether the egg is used in the research project.
9103	The licence holder is authorised to use up to 345 excess ART embryos.
9104	The licence holder may not remove from cryostorage for the purpose of conducting the activity authorised by the licence a greater number of excess ART embryos than the number specified in condition 9103.

9105	When testing each set of parameters, the licence holder is required to make an interim assessment of the results. If after the first 10 test and 10 control eggs or the first 10 test and 10 control embryos have been used, the results show poor recovery and/or poor survival of the test eggs or embryos compared to the controls and the controls are comparable to current clinical results then no more eggs or embryos may be used to test that set of parameters. In this context poor recovery or poor survival of embryos means less than 80% recovery or less than 80% survival. Poor recovery or poor survival of eggs means less than 50% recovery or less than 50% survival.
9106	In the absence of a notification provided in accordance with Condition 9406, no more excess ART embryos may be used under this licence.
9107	In the absence of a notification provided in accordance with Condition 9406, no more clinically unusable eggs may be used under this licence.

Specified Sites

Condition Number	*Condition*
9201	The licence holder must conduct the use of excess ART embryos and clinically unusable eggs 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	When recording an outcome for each egg as required by Condition 9102, the licence holder is required to use the template specified in Standard Condition 3001.
9402	The licence holder must report to the Licensing Committee within 14 days of determining that the situation described in Condition 9105 has occurred. The report must include an analysis of and reasons for the observed results and a plan for resolving the problem. Use of eggs or embryos to test the proposed plan for resolving the problem may only commence after the Licensing Committee has approved the report.
9406	If, (a) the process for obtaining regulatory approval in any jurisdiction, or (b) proposed modifications to the device or freeze protocols, or (c) approval of modifications to the device or protocols, requires additional testing then the licence holder is required to notify the Licensing Committee before commencing the testing. The notification must inform the Licensing Committee as to whether the testing requires the use of excess ART embryos or clinically unusable human eggs or both.
9407	If a notification has been made in accordance with Condition 9406, the licence holder is required to report to Licensing Committee within 14 days of the completion of the additional testing. Following this reporting, Conditions 9106 and 9107 apply until such time as a further notification is made in accordance with Condition 9406.
9408	When providing the reports required by Standard Condition 3001, the licence holder must identify any excess ART embryos and clinically unusable eggs, 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*
9505	When cryostored excess ART embryos and clinically unusable eggs are used under the licence a “cooling-off” period of at least 2 weeks must have been observed.
9506	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.
9507	Amendments to the *Participant Information and Consent Form for clinically unsuitable eggs,* the *Participant Information and Consent Form for excess ART embryos* and the *Declaration of excess clinically unsuitable eggs* 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.
9508	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.
9509	An excess ART embryo or clinically unusable egg may only be used for the training activities allowed by Condition 9701 if the people responsible for the embryo or egg have given consent for its use in the training activities in addition to consent for the activities authorised by Item 7.

Training activities included in licensed activity

Condition Number	*Condition*
9701	When excess ART embryos or clinically unsuitable eggs 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
21 March 2012 (version 2)	9402	Reworded to clarify reporting requirements
21 March 2012 (version 2)	9302	Addition of new authorised person
15 August 2013 (version 3)	9302	Removal of authorised person from list of authorised persons
15 August 2013 (version 3)	various	Update licence to reflect Sydney IVF's name change to Genea Limited
15 August 2013 (version 3)	9101, 9501, 9504, 9505	Variation to process for obtaining proper consent
15 August 2013 (version 3)	9502, 9503	Variation to documents used to obtain proper consent
28 February 2014 (version 4)	9302	Removal of authorised person from list of authorised persons
26 June 2014 (version 5)	9302	Addition of new authorised persons
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)	Expiry date	Extension of licence to 8 December 2016
1 October 2014 (version 7)	9103	Increase in number of excess ART embryos authorised for use
1 October 2014 (version 7)	9301	Add Alternate Principal Supervisor
16 October 2014 (version 8)	9302	Addition of new authorised person
14 November 2014 (version 9)	9106, 9107, 9403 – 9407	Variation to reporting requirements
26 March 2015 (version 10)	9302	Addition of new authorised person; removal of authorised person from list of authorised persons.
14 April 2015 (version 11)	9302	Addition of new authorised persons
23 June 2015 (version 12)	9302	Addition of new authorised person
25 November 2015 (version 13)	9301	New Principal Supervisor and Alternate Principal Supervisor
25 November 2015 (version 13)	9302	Removal of authorised person from list of authorised persons
25 November 2015 (version 13)	9501-9503, 9506-9508	Variation to process for obtaining proper consent
7 March 2016 (Version 14)	9302, 9303 9408 9509 9701, 9702	Addition of authorised persons Changes to reporting conditions Requirement to obtain consent Approval of training activities within licensed activity
6 April 2016 (Version 15)	9201-9203	Addition of new site for licensed activity and records storage
6 June 2016 (Version 16)	9302	Removal of authorised person from list of authorised persons
6 June 2016 (Version 16)	9302, 9303	Removal of authorised person from list of authorised persons
6 October 2016 (Version 17)	Expiry date	Extension of licence to 8 December 2018

8 March 2017 (Version 18)	9201-9203	Removal of site for licensed activity and records storage
8 March 2017 (Version 18)	9301	Departure of Principal Supervisor Approval of new Principal Supervisor
8 March 2017 (Version 18)	9302	Removal of authorised person from list of authorised persons
8 March 2017 (Version 18)	Attachment A	Removal of condition relating to an authorised person's use of excess ART embryos
7 June 2017 (Version 19)	9302	Removal of authorised person from list of authorised persons
6 November 2017 (Version 20)	9106-9107 9403-9407	Variation to reporting requirements
28 February 2018 (Version 21)	9302	Removal of authorised person from list of authorised persons
7 December 2018 (Version 22)	9302	Removal of authorised person from list of authorised persons
7 December 2018 (Version 22)	9302	Addition of authorised person
7 December 2018 (Version 22)	Expiry date	Extension of licence to 8 December 2021
10 January 2020 (Version 23)	9302	Removal of authorised person from list of authorised persons
10 August 2020 (Version 24)	9301	Departure of Principal Supervisor Approval of new Principal Supervisor