Australian Government
National Health and Medical Research Council

Research Involving Human Embryos Act 2002

Embryo Research Licensing Committee of 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:	309726
2.	Licence Holder:	Genea Limited
3.	Licence Title:	Use of excess ART embryos for training in an alternate biopsy method (day five hatch and biopsy)
4.	Date of Issue:	3 June 2019
5.	Licence begins:	3 June 2019
6.	Licence ends:	2 June 2022
7.	Activity authorised by the licence	This licence authorises embryologists to use excess ART embryos to attain proficiency in day five embryo biopsy. 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 Activity	The goal of the licensed activity is to allow embryologists to achieve competence in an alternative technique of embryo biopsy through the use of limited numbers of excess ART embryos.
9.	Standard Conditions:	All conditions that are specified in the document *Standard Conditions of Licence*
10.	Special Conditions:	All conditions that are specified in the *Special Conditions for Licence 309726*

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 309726

Licence Number:	309726
Licence Holder:	Genea Limited
Licence Title:	Use of excess ART embryos for training in an alternate biopsy method (day five hatch and biopsy)

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 excess ART embryos

Condition Number	*Condition*
9101	Except as allowed by Condition 9601, a maximum of 20 suitable excess ART embryos may be used to train each trainee authorised by condition 9303 in the technique of day five hatch and biopsy, hereafter blastocyst-stage biopsy.
9102	A maximum of two of the suitable excess ART embryos described in Condition 9101, may be used by the Alternate Principal Supervisor to demonstrate the hatch and biopsy technique to each trainee.
9103	An excess ART embryo, which was frozen at blastocyst stage, is taken to be suitable for the purposes of condition 9101 if greater than 50% of its blastomeres are intact immediately following thawing.
9104	A maximum of 25 excess ART embryos may be removed from cryostorage and thawed in order to obtain the 20 suitable blastocyst-stage embryos for the purposes of training each trainee.
9105	When a trainee has used 20 suitable blastocyst-stage embryos or has reached proficiency as described in Condition 9402, the licence holder is not permitted to thaw any more excess ART embryos for that trainee.
9106	The training of a trainee may not commence unless the licence holder has obtained proper consent to use at least 15 excess ART embryos in respect of that trainee.
9107	The excess ART embryos donated to this licence must not be used for any purpose except training in blastocyst-stage embryo biopsy. Any embryo which is not suitable for the purposes of Condition 9101 must be discarded when it is determined to be unsuitable.
9108	An excess ART embryo is deemed to have survived blastocyst biopsy if it does not degenerate and has re-expanded one to four hours after biopsy.

Specified Sites

Condition Number	*Condition*
9201	The licence holder must conduct the use 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 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

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 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.
9303	This licence authorises those people listed as trainees in **Attachment A** to be trained in the technique of blastocyst-stage embryo biopsy. Other trainees may be permitted to undertake training in the future provided the requirements of Condition 9305 are satisfied in relation to each proposed trainee.
9304	The Principal Supervisor must ensure that, before any trainee uses an excess human ART embryo pursuant to this licence, that trainee has demonstrated skill in the micromanipulation of animal and/or human gametes and embryos.
9305	A trainee must not use an excess ART embryo for training as authorised by this licence, unless the licence holder has first: (i) submitted an application to the NHMRC Licensing Committee as specified at http://www.nhmrc.gov.au/research/information-licence-holders for that trainee to use excess ART embryos as authorised by this licence; and (ii) received approval in writing from the NHMRC Licensing Committee for the training of that trainee pursuant to this licence.
9306	The designated Alternate Principal Supervisor must oversee all blastocyst biopsies conducted under this licence.
9307	This licence authorises the designated Alternate Principal Supervisor to use excess ART embryos as described in Condition 9101.

Reporting

9401	When providing the reports required by condition 3001, the licence holder must provide the following information to the NHMRC Licensing Committee in addition to the requirements specified in condition 3001: (i) the name of each individual who has received training as authorised by this licence during the reporting period; (ii) how many suitable embryos have been used for or by each trainee; (iii) how many suitable embryos have been used by the designated Alternate Principal Supervisor for each trainee; and (iv) the progress of the training, including a summary of results for any aneuploidy screening conducted under this licence.
9402	The licence holder is required to report to the NHMRC Licensing Committee within 14 days of a trainee reaching proficiency in blastocyst-stage biopsy. For the purposes of this condition the licence holder has defined proficiency as: (a) biopsy of at least three embryos which survive as described in Condition 9108, where the competence, confidence, repeatability and speed demonstrated by the trainee is acceptable to the Alternate Principal Supervisor; and, for those trainees not already proficient in tissue transfer: (b) successful transfer of cells to sample tubes in a minimum of five consecutive attempts.
9403	The licence holder is required to notify the NHMRC Licensing Committee in writing within 14 days if a trainee uses more than 20 suitable embryos as permitted by Condition 9601.

Conditions relating to proper consent

Condition Number	*Condition*
9501	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.
9502	Amendments to the *Participant Information and Consent Form* for Licence 309726 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.
9503	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	Licence holders are required to manage the number of excess ART embryos thawed for use under the licence to limit the likelihood of obtaining greater than the allowable number of suitable embryos per trainee. In the event that a trainee has reached proficiency or has obtained 20 suitable embryos and suitable embryos remain in culture: (a) the excess suitable embryos may be transferred to another trainee who has not yet biopsied 20 suitable embryos or reached proficiency; or (b) where the excess suitable embryos cannot be used by another trainee, the trainee for whom the embryos were initially thawed may use the excess embryos for additional practice in the technique. In this case the total number of embryos used for or by the trainee must not exceed 25.